IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

COOK INCORPORATED,	)	
	)	
Plaintiff,	)	Case No.: 1:09-cv-1248-TWP-TAB
v.	)	
	)	
ENDOLOGIX, INC.,	)	DEMAND FOR JURY TRIAL
	)	
Defendant.	)	

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Cook Incorporated ("Cook"), through counsel, brings this Amended Complaint against Defendant Endologix, Inc. ("Endologix"), as follows:

JURISDICTION AND VENUE

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

2. This Court has subject matter over this action under 28 U.S.C. §§ 1331 and 1338(a).

3. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

PARTIES

4. Cook is now, and at all times mentioned in this Amended Complaint has been, an Indiana corporation with a principal place of business of 750 Daniels Way, Bloomington, Indiana 47402.

5. Endologix is a corporation of the State of Delaware, having its principal place of business of 11 Studebaker, Irvine, California 92618.

6. Endologix manufactures delivery systems sold under the name of the IntuiTrak system in California, and sells and supplies the same throughout the United States, including the State of Indiana and this District, and abroad.

7. Endologix manufactures stent grafts sold under the name Powerlink stent graft in California, and sells and supplies the same throughout the United States, including the State of Indiana and this District, and abroad.

THE PATENTS IN SUIT

8. On May 26, 1998, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 5,755,777, entitled "Expandable Transluminal Graft Prosthesis for Repair of Aneurysm." On July 20, 2010, the United States Patent and Trademark Office duly and legally issued a Reexamination Certificate for U.S. Patent No. 5,755,777. A copy of U.S. Patent No. 5,755,777 and the Reexamination Certificate for U.S. Patent No. 5,755,777 (hereinafter the "'777 Patent") is attached as Exhibit A to this Amended Complaint. Cook is the owner of the '777 Patent.

9. On July 30, 1991, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 5,035,706 (the "'706 Patent"), entitled "Percutaneous Stent and Method for Retrieval Thereof." On November 3, 1992, the United States Patent and Trademark Office duly and legally issued a Certificate of Correction for U.S. Patent No. 5,035,706. On April 20, 2010, the United States Patent and Trademark Office duly and legally issued a Reexamination Certificate for U.S. Patent No. 5,035,706. A copy of U.S. Patent No. 5,035,706, the Certificate of Correction for U.S. Patent No. 5,035,706, and the Reexamination Certificate for U.S. Patent No. 5,035,706 (hereinafter the "'706 Patent") is attached as Exhibit B to this Amended Complaint. Cook is the owner of the '706 Patent.

10. On November 16, 2009, Endologix filed a request for an *Ex Parte* Reexamination of U.S. Patent No. 5,755,777, and that request was granted by the United States Patent and Trademark Office on December 10, 2009. On or about April 16, 2010, Endologix received the Notice of Intent to Issue a Reexamination Certificate in the *Ex Parte* Reexamination of U.S. Patent No. 5,755,777 from the United States Patent and Trademark Office. On July 20, 2010, the United States Patent and Trademark Office issued the Reexamination Certificate for U.S. Patent No. 5,755,777 that states that the United States Patent and Trademark Office determined that claims 1, and 21 through 33 were patentable.

11. On November 23, 2009, Endologix filed a request for an *Ex Parte* Reexamination of U.S. Patent No. 5,035,706, and that request was granted by the United States Patent and Trademark Office on December 22, 2009. On or about February 15, 2010, Endologix received the Notice of Intent to Issue a Reexamination Certificate in the *Ex Parte* Reexamination of U.S. Patent No. 5,035,706 from the United States Patent and Trademark Office. On April 20, 2010, the United States Patent and Trademark Office issued the Reexamination Certificate for U.S. Patent No. 5,035,706 that states that the United States Patent and Trademark Office determined that claims 6 and 12 were patentable.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 5,755,777

12. Endologix repeats and re-alleges each and every allegation contained in the above paragraphs as if fully set forth herein

13. Endologix has been and is still infringing claims 1 and 21 - 33 of the ’777 Patent by making, using, selling, importing, exporting or offering to sell in the United States, delivery systems, including products sold under the name of the IntuiTrak system, which embody, incorporate or otherwise practice the claimed inventions.

14. Use by third parties of the aforesaid delivery systems obtained from or through Endologix infringes the '777 Patent. Endologix's activities constitute active inducement infringement of the '777 Patent because, with knowledge, reckless disregard, or deliberate indifference amounting to knowledge of the infringement of the '777 Patent, Endologix has provided and continues to provide delivery systems and/or components thereof to others for use, promotes and continues to promote, and/or instructed and continues to instruct others in infringement of the '777 Patent.

15. Endologix's activities constitute contributory infringement of the '777 Patent because Endologix makes, uses, sells, imports, exports or offers to sell the aforesaid delivery systems and/or components thereof with knowledge, reckless disregard, or deliberate indifference amounting to knowledge of the infringement of the '777 Patent and said products and/or components thereof constitute a material part of the '777 Patent and are especially made or especially adapted for use in infringement of the '777 Patent, and said delivery systems and/or components thereof are not a staple article or commodity of commerce suitable for substantial non-infringing use.

16. Endologix has known of U.S. Patent No. 5,755,777 since no later than the service of the original Complaint on October 8, 2009, and Endologix has had notice of the reexamination proceedings involving this Patent, including the Notice of Intent to Issue a Reexamination Certificate issued by the United States Patent and Trademark Office on April 14, 2010 and the Reexamination Certificate issued by the United States Patent and Trademark Office on July 20, 2010, and since this knowledge, Endologix has continued to infringe the '777 Patent even after the reexamination of that Patent concluded. Endologix's continued infringement of the '777 Patent, despite notice of the '777 Patent, and despite notice of the patentability of the claims of the '777 Patent from the reexamination proceeding, establish that Endologix is objectively reckless and disregarding an objectively high

likelihood that it infringes the '777 Patent. Endologix's infringement of the '777 Patent has been and continues to be deliberate, in disregard of the '777 Patent, and willful.

17. As a direct and proximate result of Endologix's infringement of the '777 Patent, Cook has been and continues to be damaged in its business and property, including the loss of revenues in an amount to be determined at trial.

18. Endologix has caused damage by its acts of infringement of the '777 Patent, and Endologix will cause additional damages and irreparable harm unless the Court enjoins Endologix from continuing such infringing acts and initiating such acts in the future.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 5,035,706

19. Endologix repeats and re-alleges each and every allegation contained in the above paragraphs as if fully set forth herein.

20. Endologix has infringed claims 6 and 12 of the '706 Patent by making, using, selling, importing, exporting or offering to sell in the United States, stent grafts, including products sold under the name of the Powerlink stent graft, which embody, incorporate or otherwise practice the claimed inventions.

21. Use by third parties of the aforesaid stent grafts obtained from or through Endologix infringed the '706 Patent. Endologix's activities constituted active inducement of the '706 Patent because, with knowledge, reckless disregard, or deliberate indifference amounting to knowledge of the infringement of the '706 Patent, Endologix has provided stent grafts to others for use, promoted, and/or instructed others in infringement of the '706 Patent.

22. Endologix has known of U.S. Patent No. 5,035,706 since no later than the service of the original Complaint on October 8, 2009, and despite this knowledge, Endologix continued to infringe the '706 Patent. Instead of ceasing its infringement, Endologix filed a request for *Ex Parte* Reexamination on November 23, 2009, and without substantive input from Cook in the

reexamination proceeding, the United States Patent and Trademark Office confirmed the patentability of claims 6 and 12 of the '706 Patent. The confirmation of claims 6 and 12 of the '706 Patent in the reexamination proceeding and Endologix's infringement with knowledge of the '706 Patent, establish that Endologix was objectively reckless and disregarded an objectively high likelihood that its conduct infringed the '706 Patent. Endologix's infringement of the '706 Patent has been deliberate, in disregard of the '706 Patent, and willful.

23. As a direct and proximate result of Endologix's infringement of the '706 Patent, Cook has been and continues to be damaged in its business and property, including the loss of revenues in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, by reason of the foregoing, Cook respectfully requests that this Court enter judgment against Defendant Endologix, Inc. that:

(a) Endologix has infringed the '777 Patent and the '706 Patent;

(b) Endologix, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with it, be preliminarily and/or permanently enjoined from infringing the '777 Patent during the remaining term thereof, pursuant to 35 U.S.C. § 283;

(c) Endologix pay damages adequate to compensate for the infringement of the '777 Patent and '706 Patent, including interest and costs, pursuant to 35 U.S.C. § 284;

(d) Increasing the damages up to three times the amount found or assessed for Endologix's willful acts of infringement pursuant to 35 U.S.C. § 284;

(e) Finding this to be an exceptional case and awarding reasonable attorneys fees to Cook pursuant to 35 U.S.C. § 285; and

(f) Cook is granted such other and further relief as the Court may deem just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff Cook Incorporated hereby demands a trial by jury on all issues triable of right by jury.

Dated: July 30, 2010

Respectfully submitted,

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Attorneys for Plaintiff,
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Exhibit A

US005755777A

United States Patent [19]

Chuter

[11] Patent Number: 5,755,777

[45] Date of Patent: May 26, 1998

[54] **EXPANDABLE TRANSLUMINAL GRAFT PROSTHESIS FOR REPAIR OF ANEURYSM**

[75] Inventor: **Timothy A. Chuter**, Pittsford, England

[73] Assignee: **Cook Incorporated**, Bloomington, Ind.

[21] Appl. No.: **727,771**

[22] Filed: **Oct. 8, 1996**

Related U.S. Application Data

[63] Continuation of Ser. No. 173,148, Dec. 22, 1993, Pat. No. 5,562,726, which is a continuation-in-part of Ser. No. 868,792, Apr. 15, 1992, abandoned, which is a continuation-in-part of Ser. No. 782,696, Oct. 25, 1991, abandoned.

[51] **Int. Cl.**[6] **A61F 2/06**; A61M 29/00

[52] **U.S. Cl.** **623/1**; 606/198; 606/195

[58] **Field of Search** 623/1, 11, 12; 606/194, 195, 198; 604/96

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(List continued on next page.)

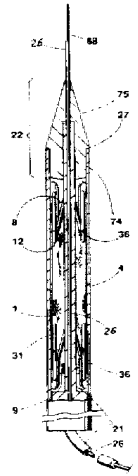
Primary Examiner—Debra S. Brittingham

Attorney, Agent, or Firm—Richard J. Godlewski

[57] **ABSTRACT**

A transluminal grafting system for grafting a prosthesis to the wall of a lumen includes a tubular graft provided with spring assemblies and anchoring barbs. The prosthesis is mounted on an apertured tubular carrier and a central control means is inserted into the bore of the apertured carrier. Mooring loops are attached to the prosthesis, pass through the apertures of the tubular carrier, and engage the central control means. An introducer sheath covers the system for smooth insertion into a lumen. When the graft has been positioned, the central control means maintains the axial position of the prosthesis. When the introducer sheath is pulled, the prosthesis is exposed and the spring assemblies return to an expanded state and anchor the graft against the internal wall of the lumen.

20 Claims, 18 Drawing Sheets



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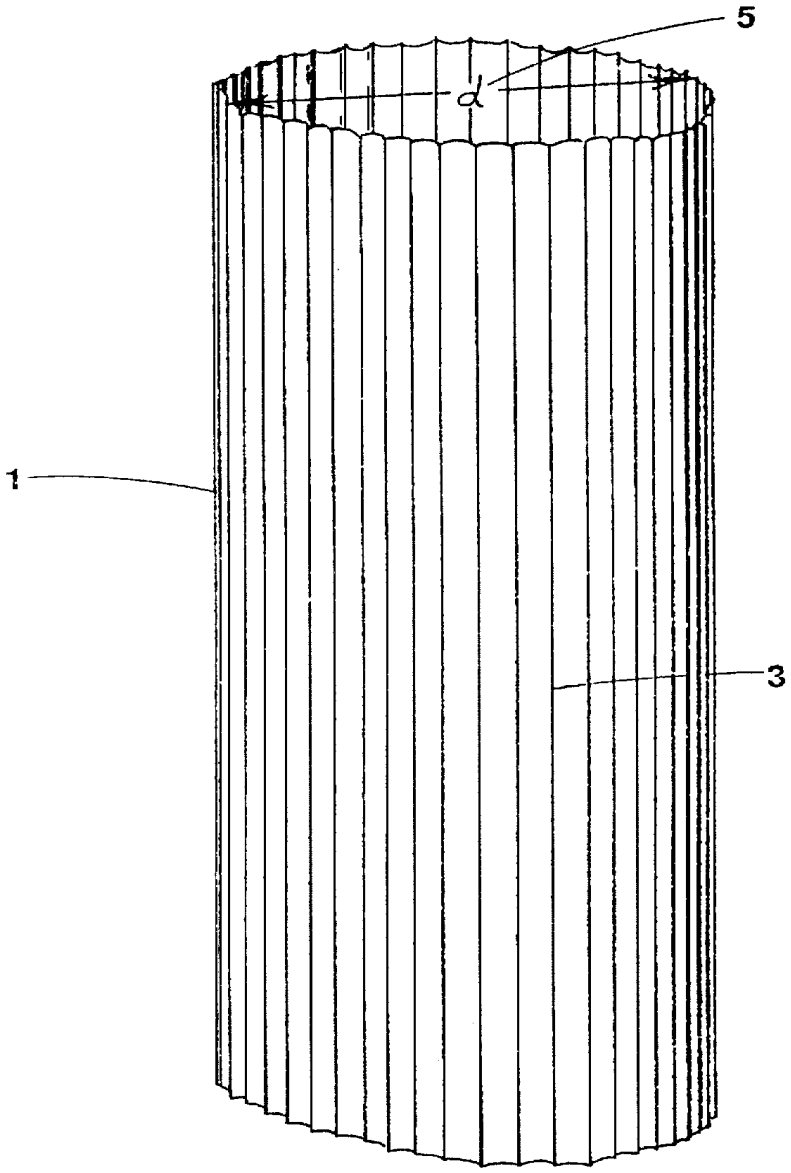

Fig. 1

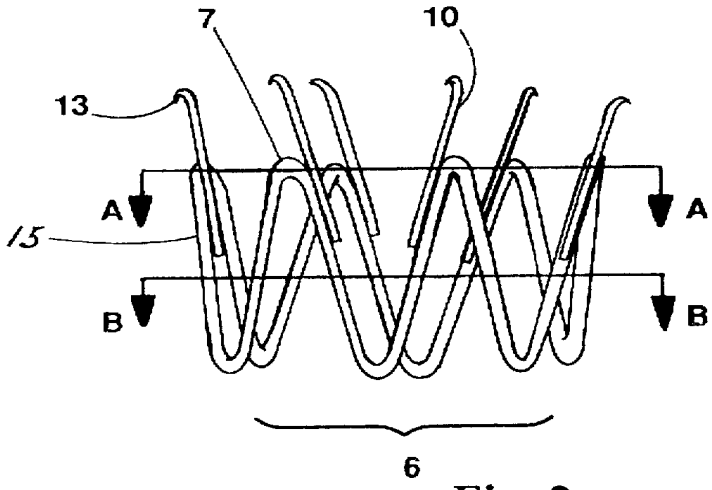

Fig. 2

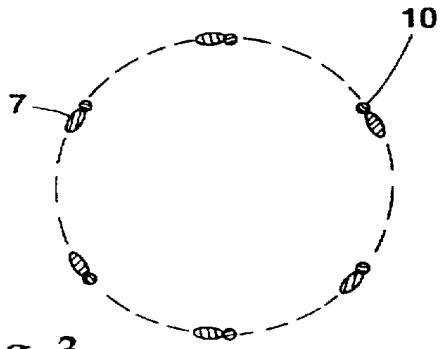

Fig. 3

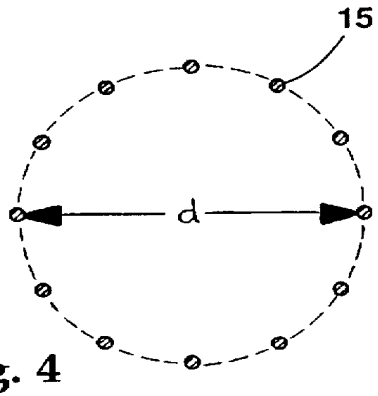

Fig. 4

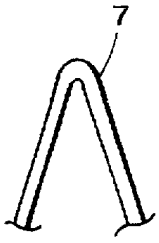

Fig. 5A

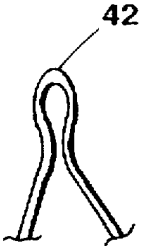

Fig. 5B

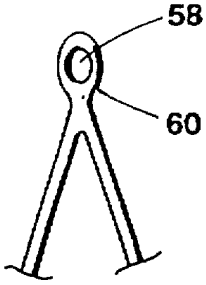

Fig. 5C

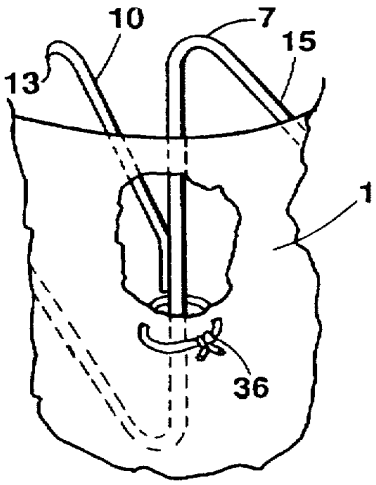

Fig. 6

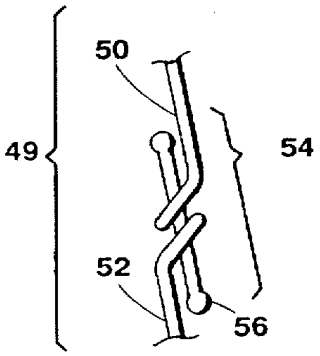

Fig. 7

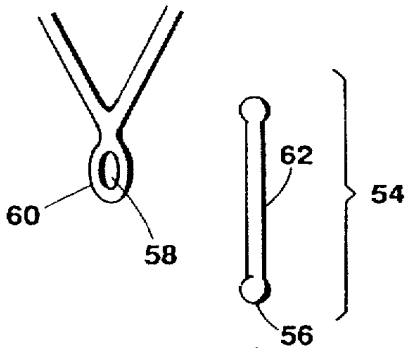

Fig. 8

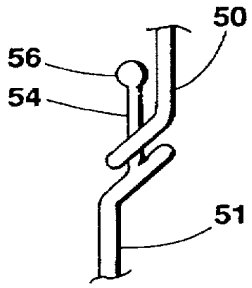

Fig. 10

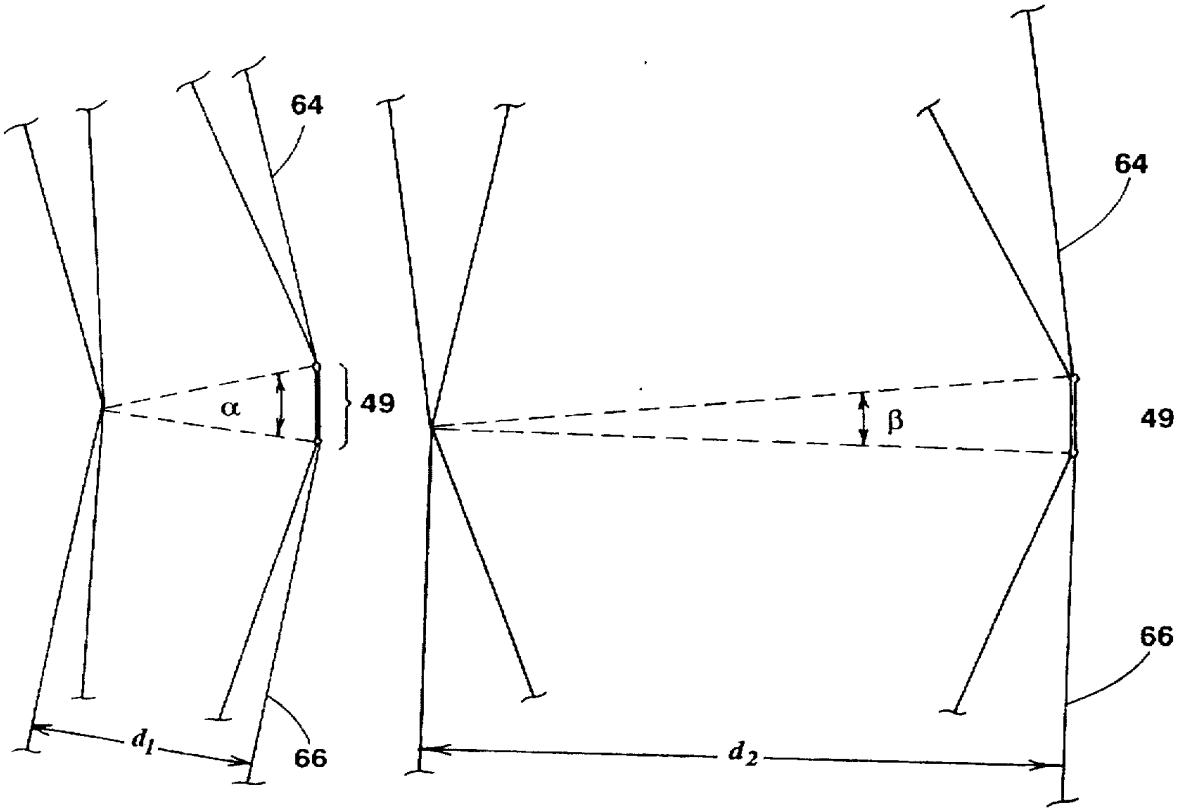

Fig. 9A

Fig. 9B

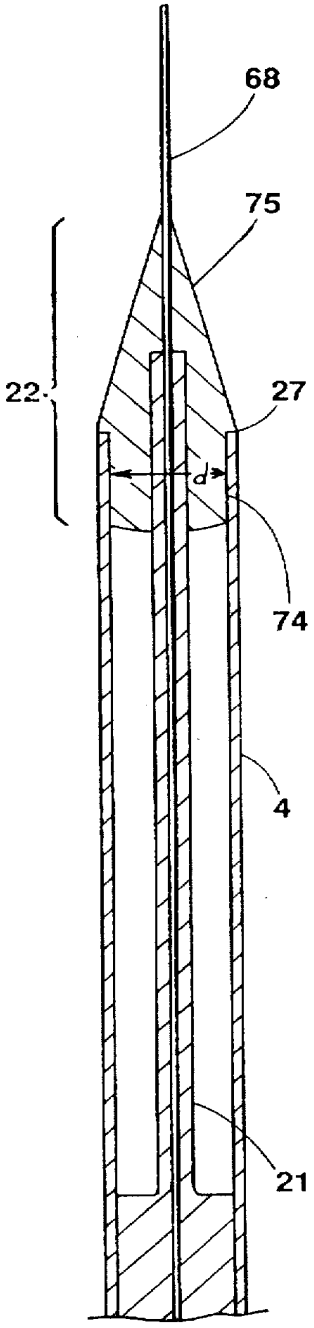

Fig. 11

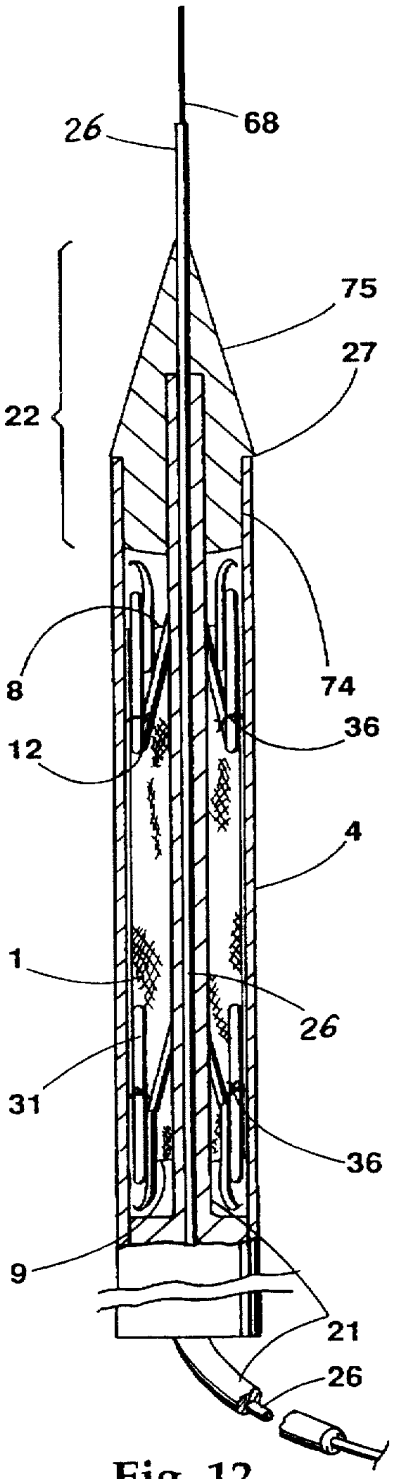

Fig. 12

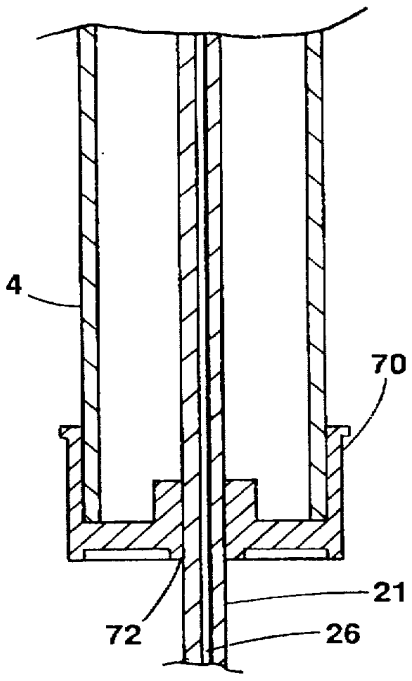

Fig. 13

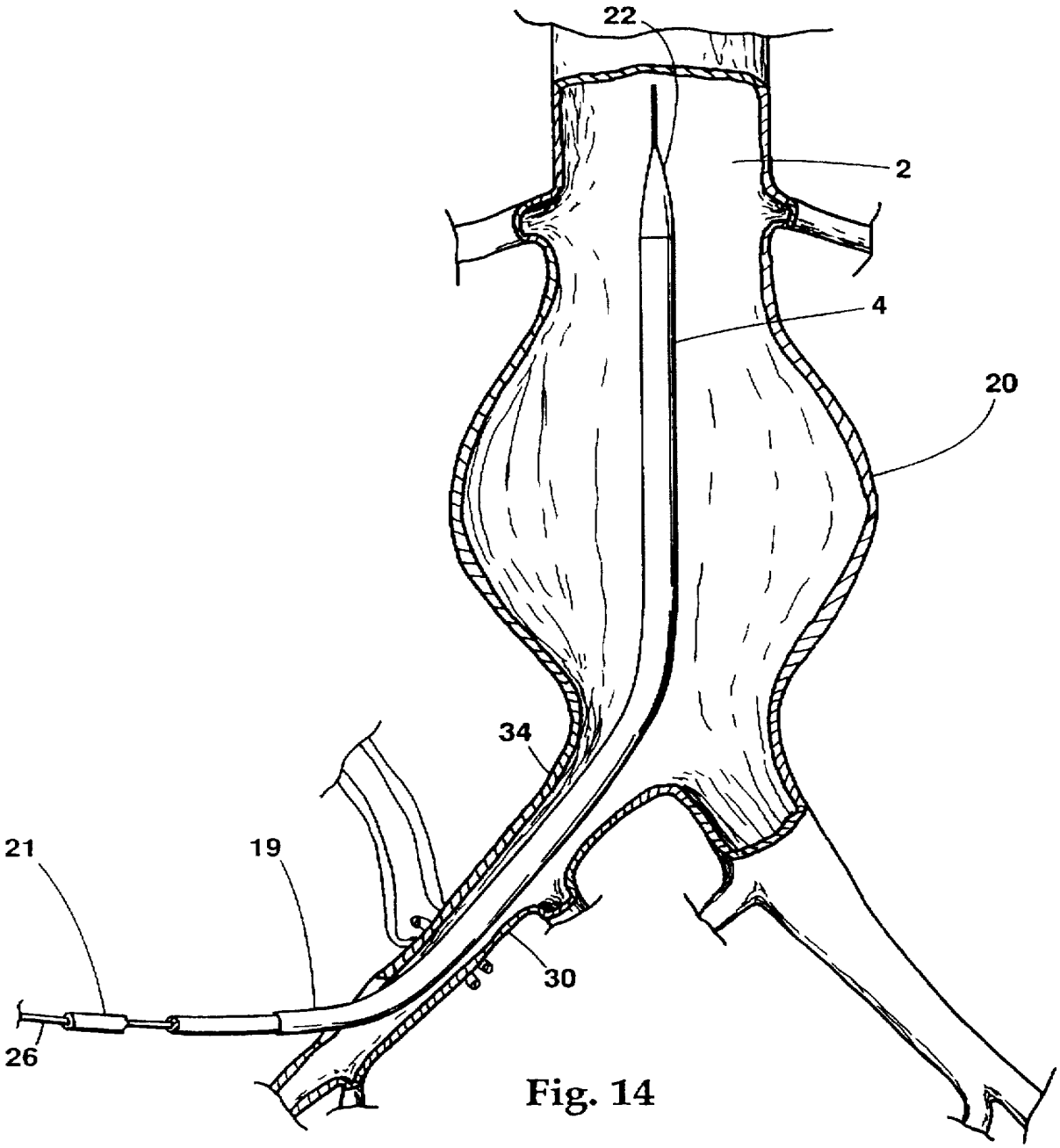

Fig. 14

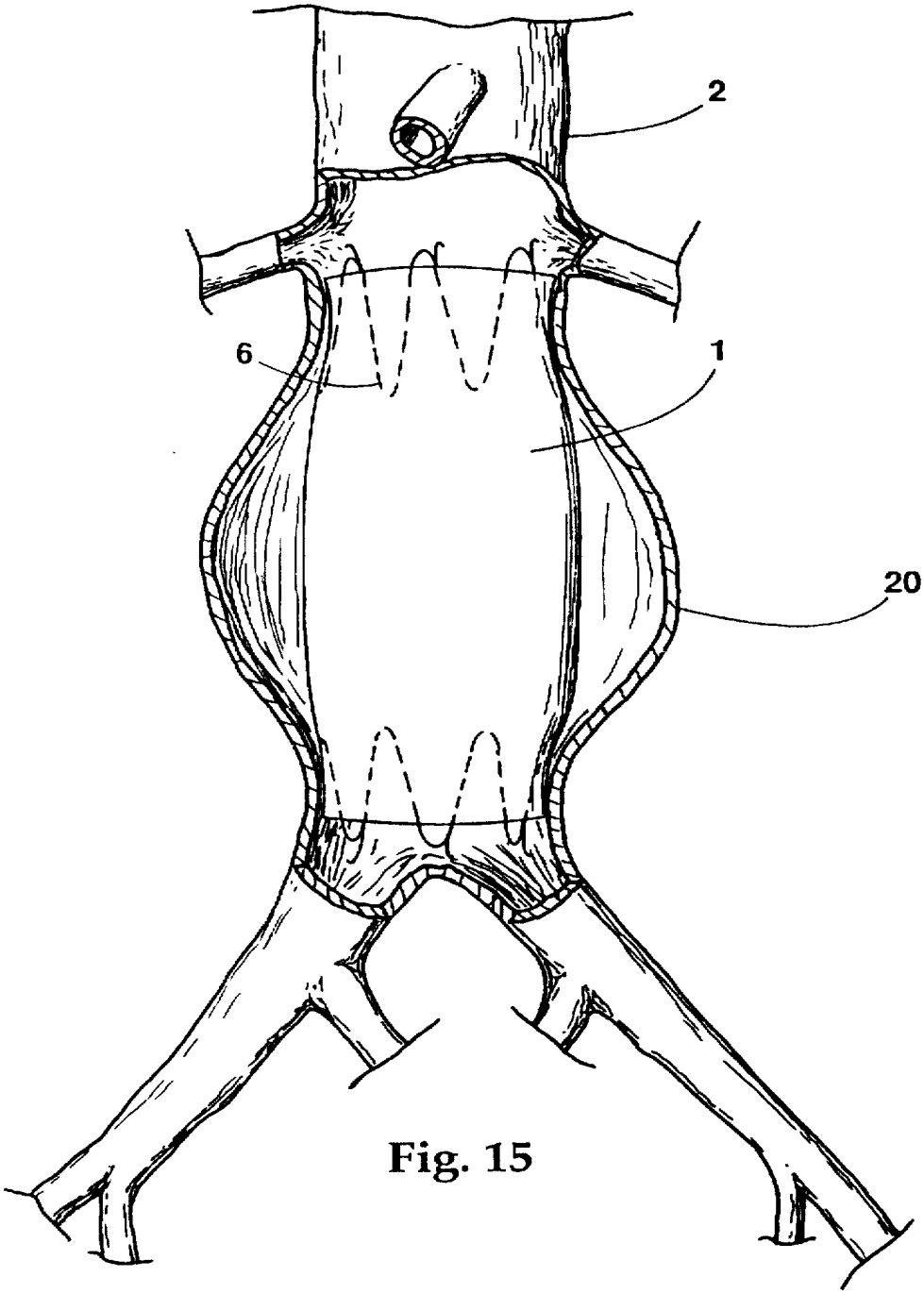

Fig. 15

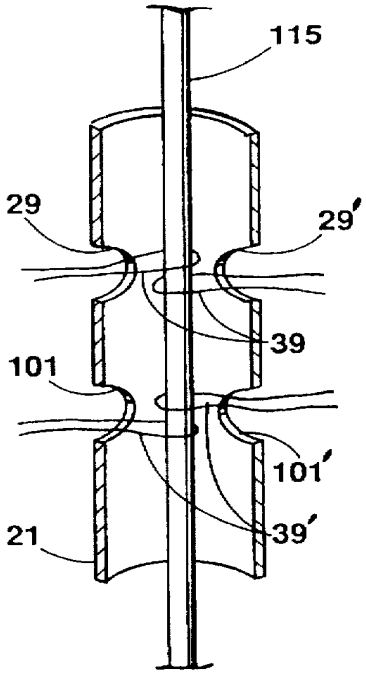

Fig. 16

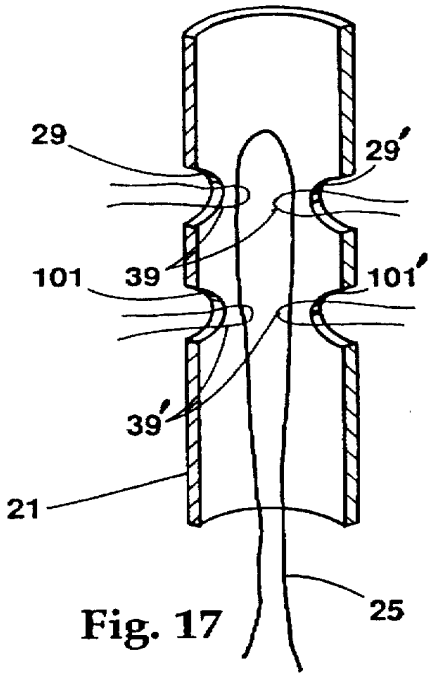

Fig. 17

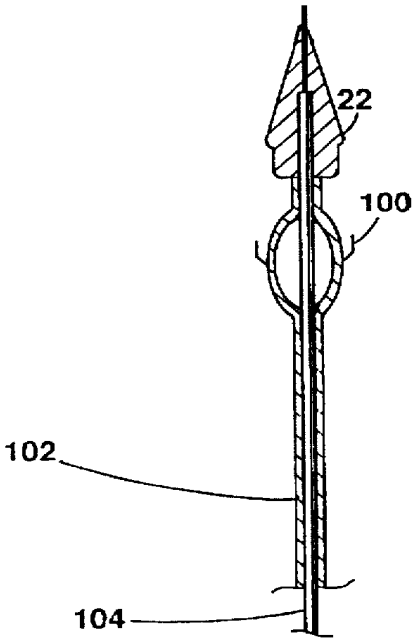

Fig. 18

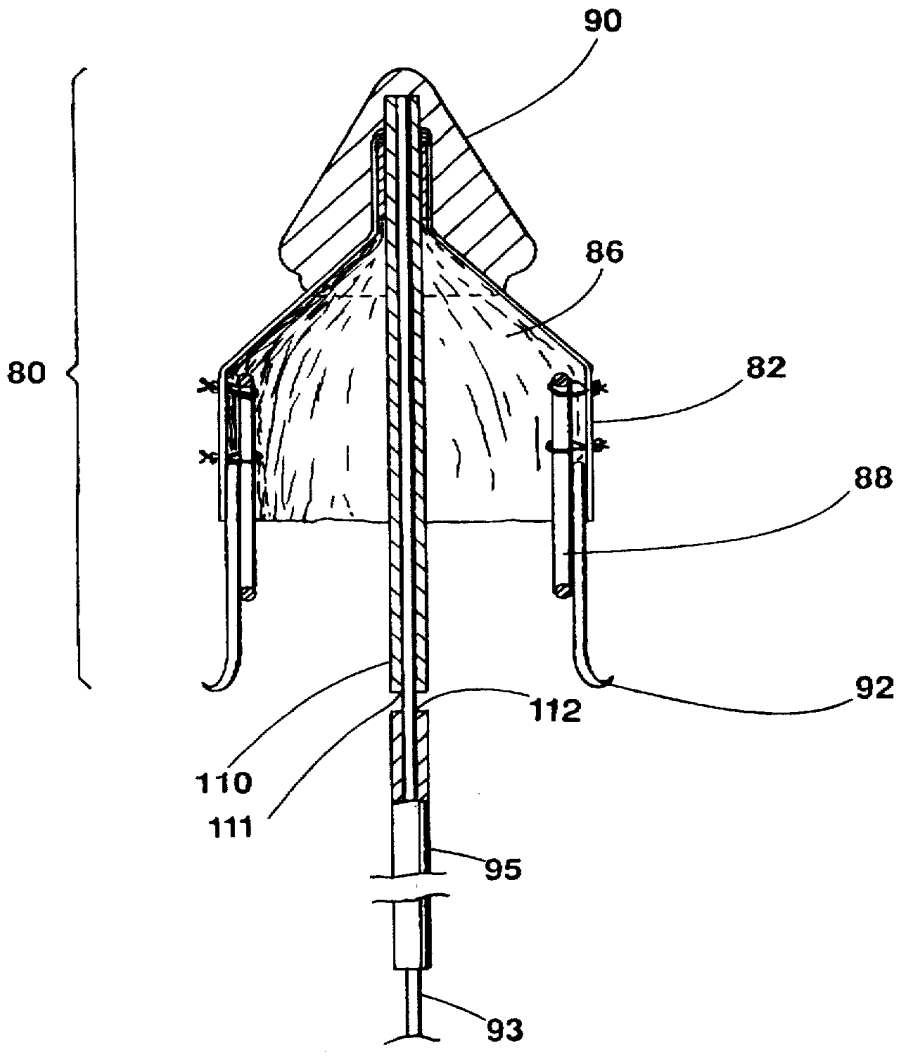

Fig. 19

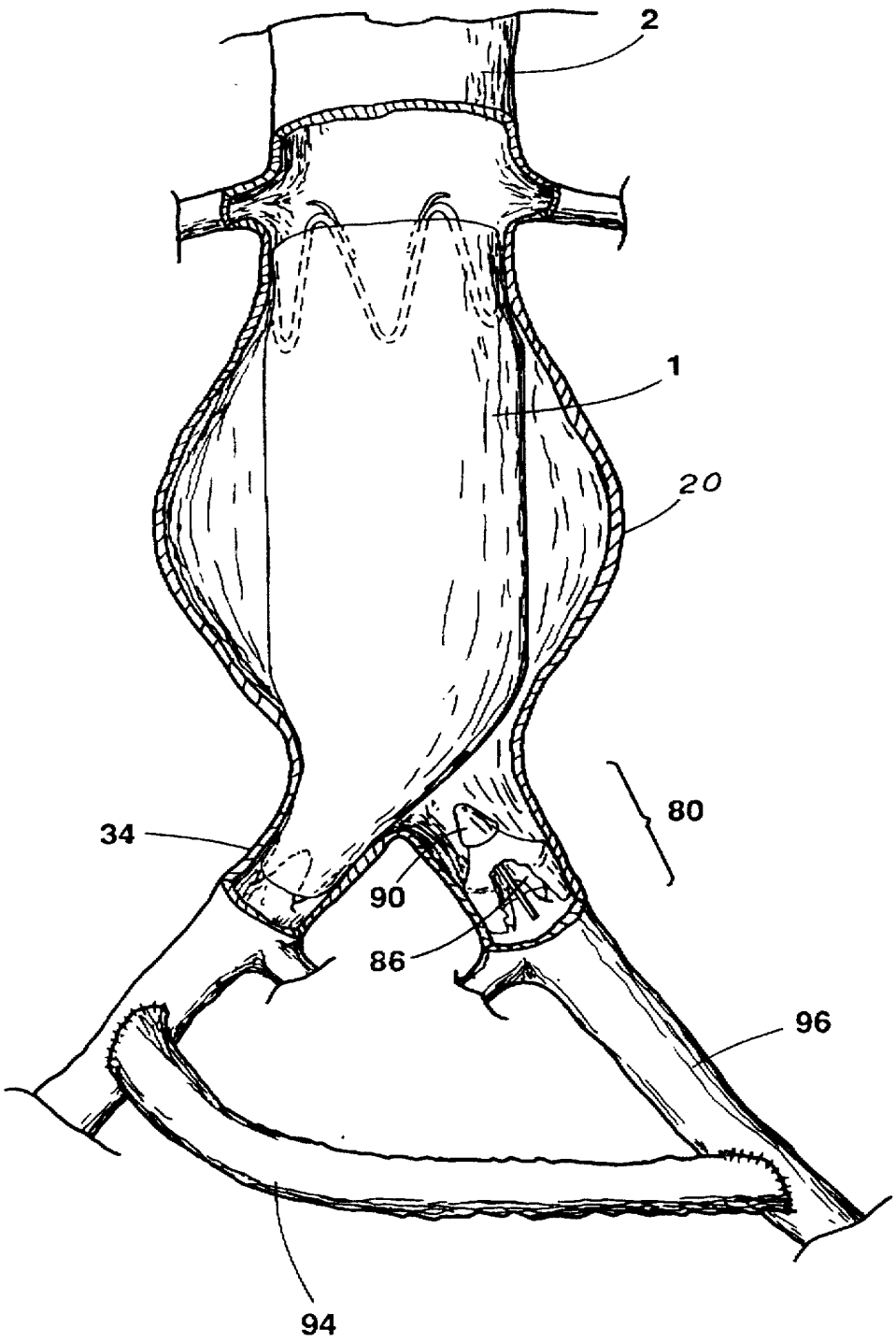

Fig. 20

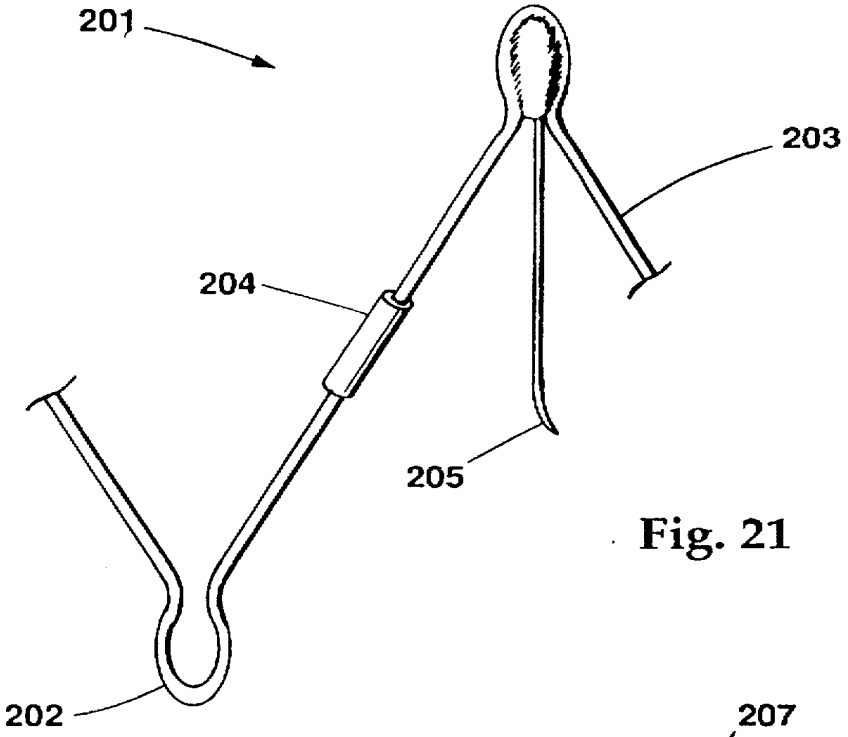
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Fig. 21

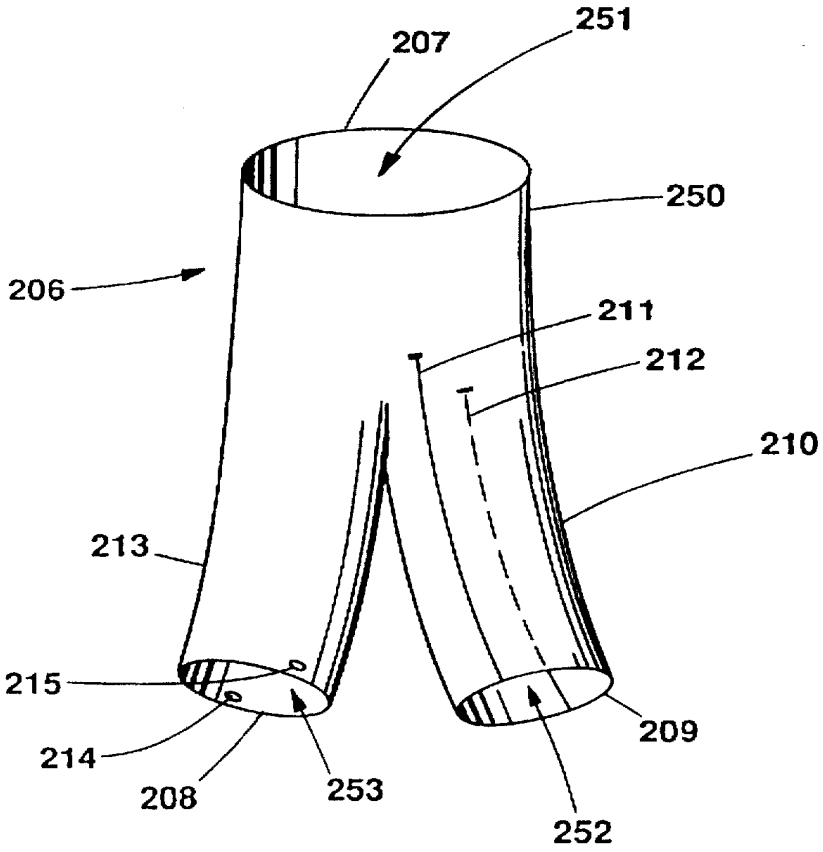
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Fig. 22

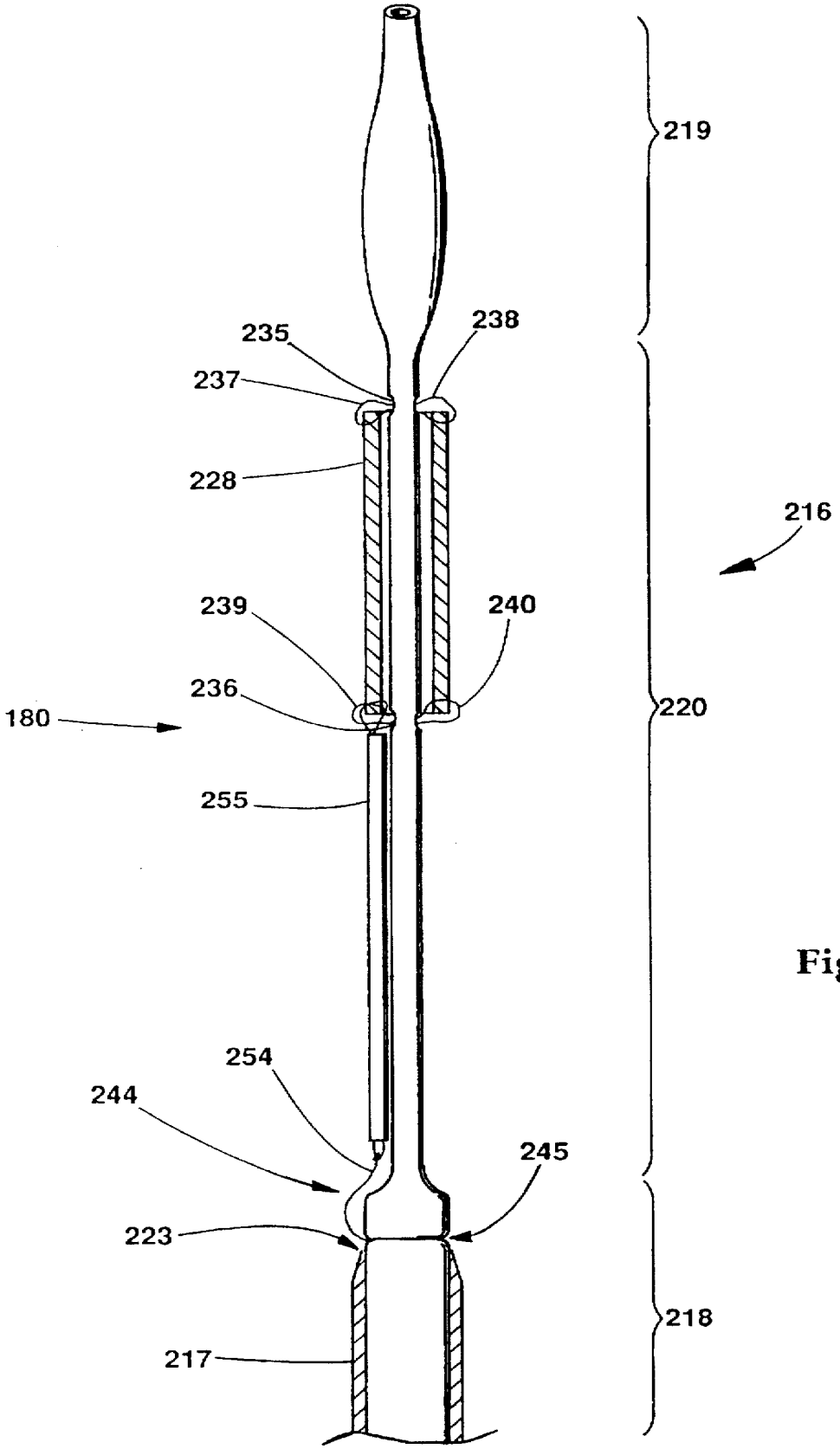
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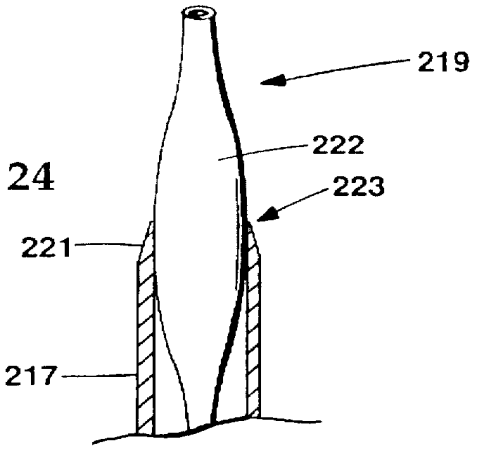
Fig. 23



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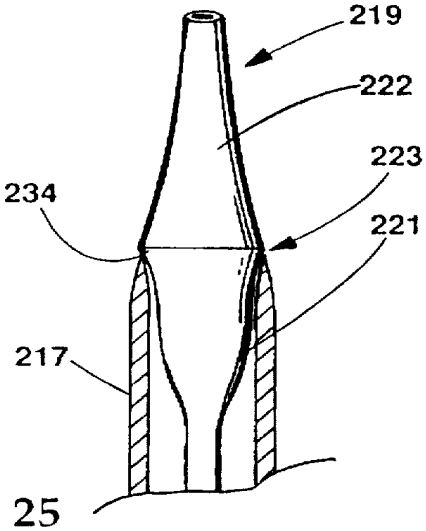

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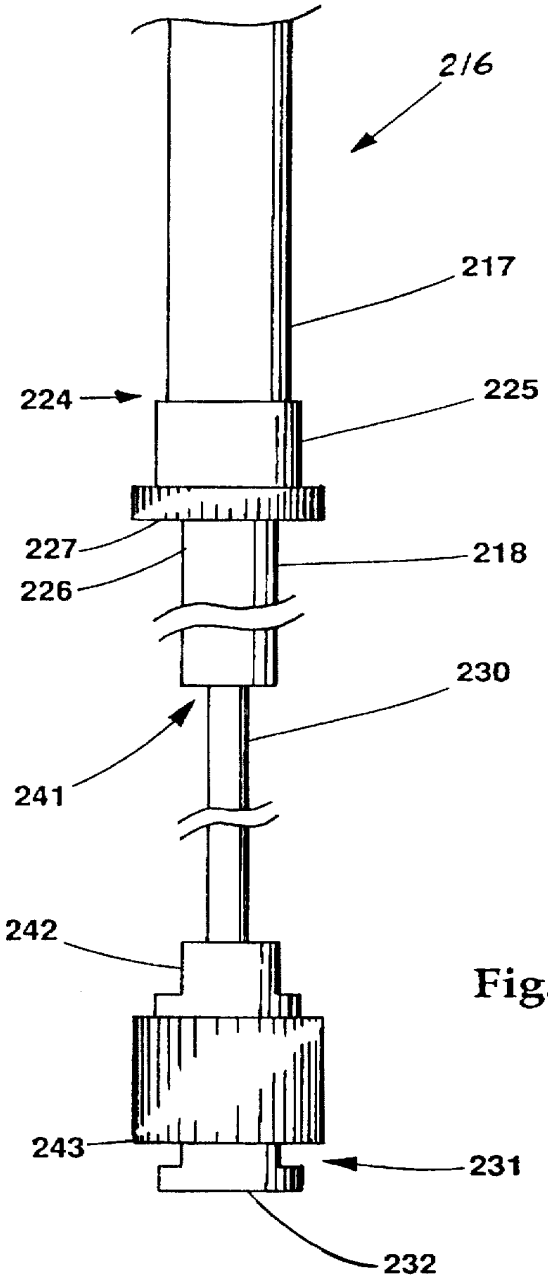

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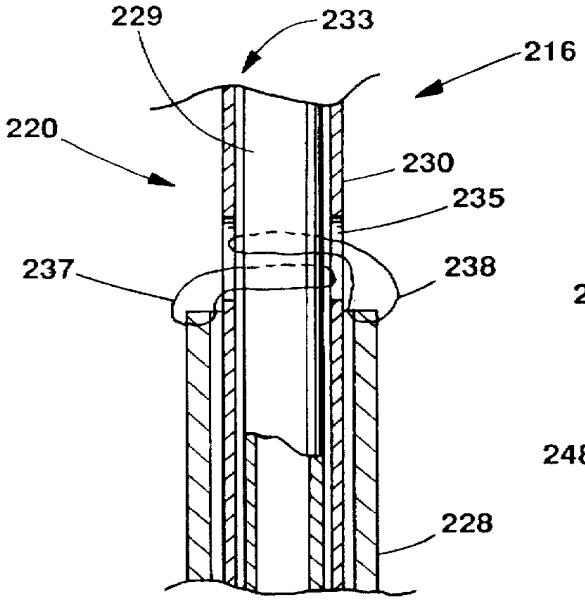

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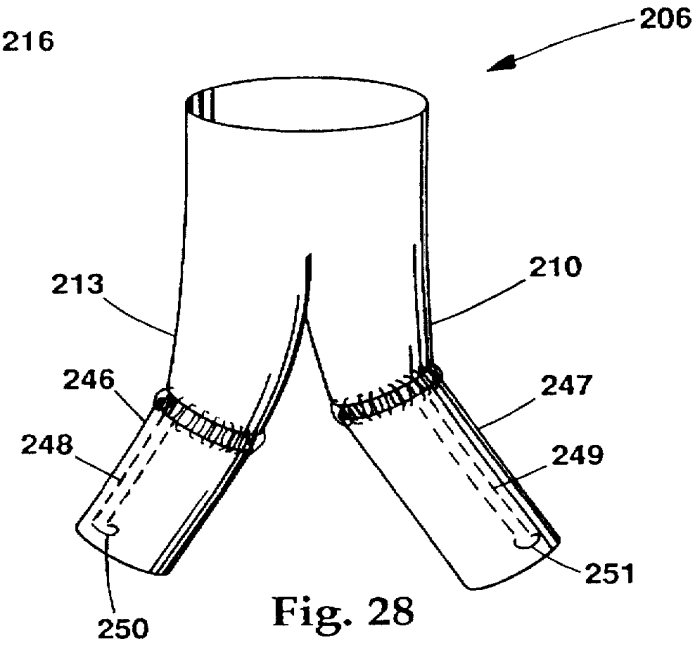

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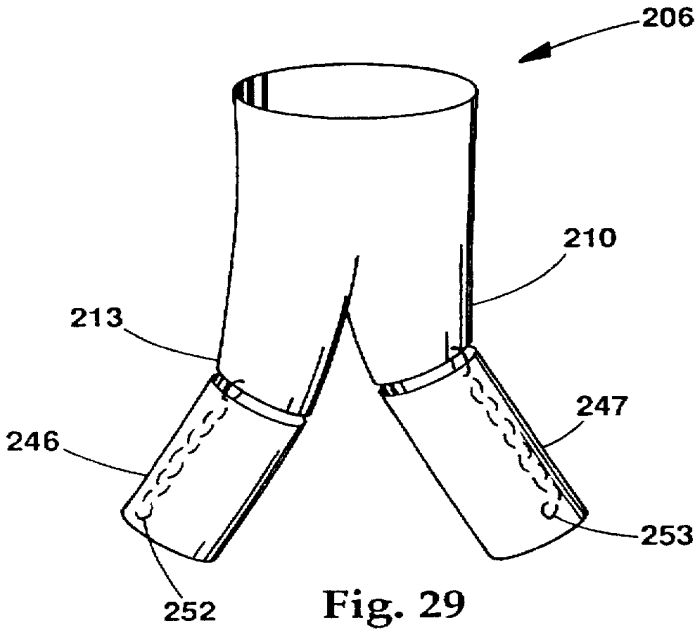

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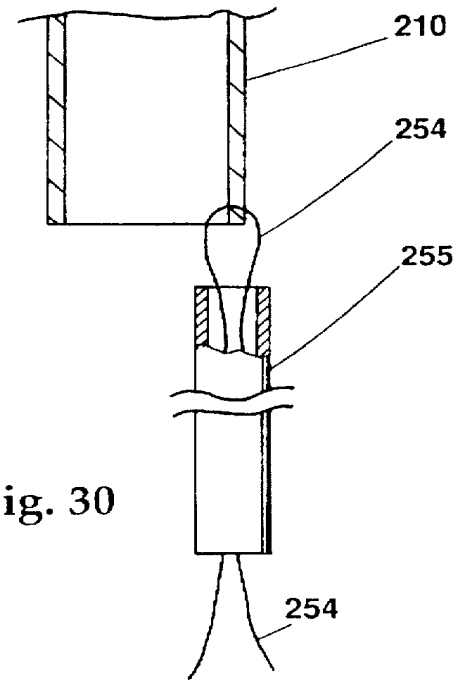

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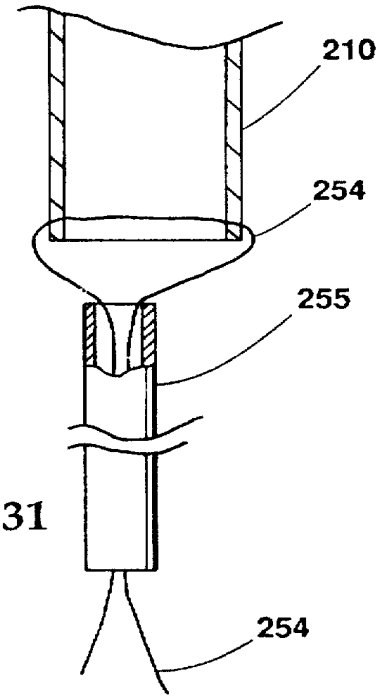

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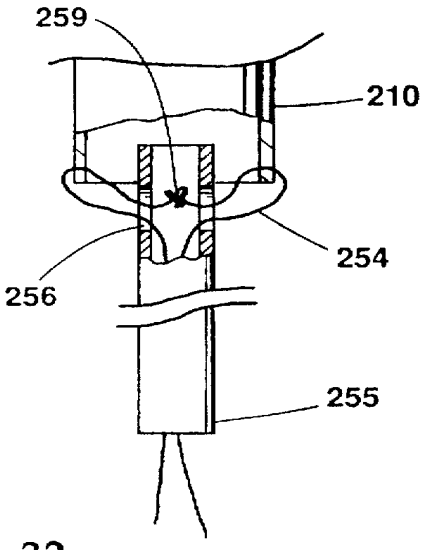


Fig. 32

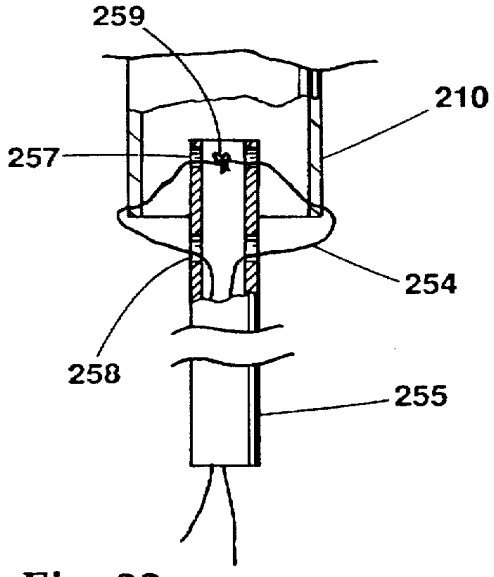


Fig. 33

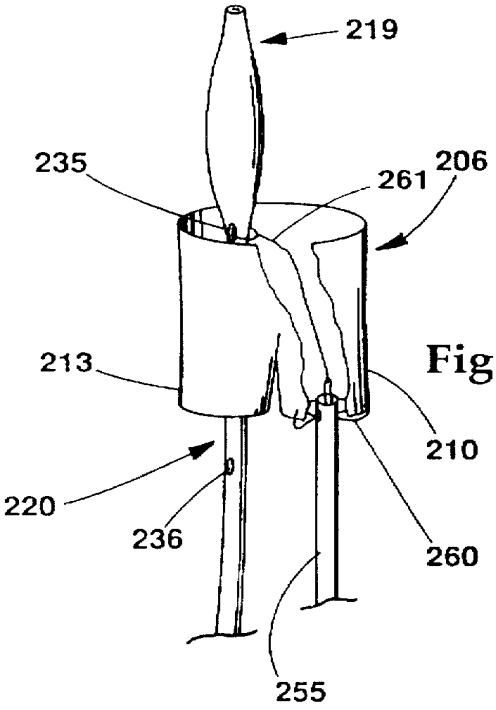


Fig. 34

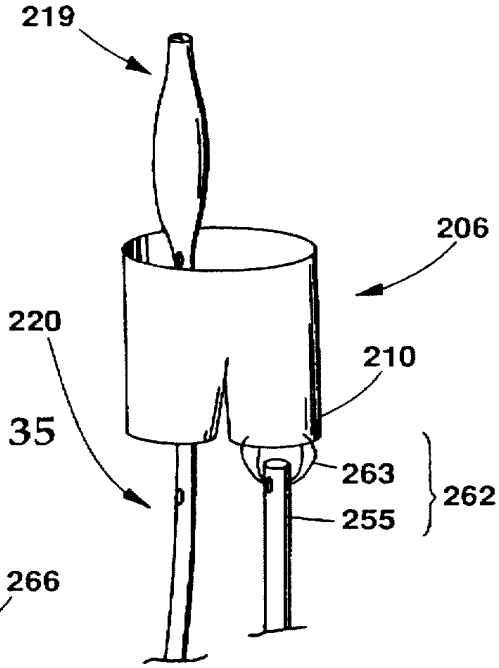


Fig. 35

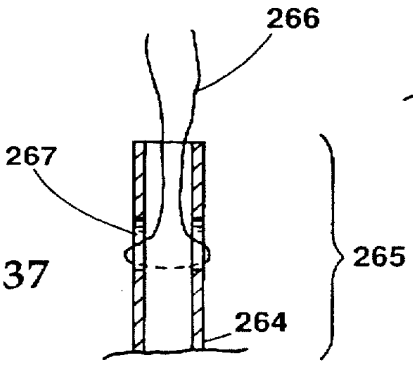


Fig. 37

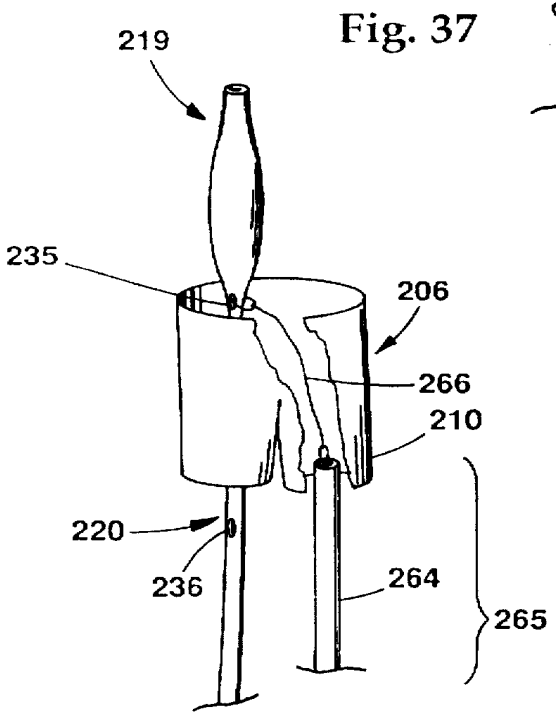


Fig. 36

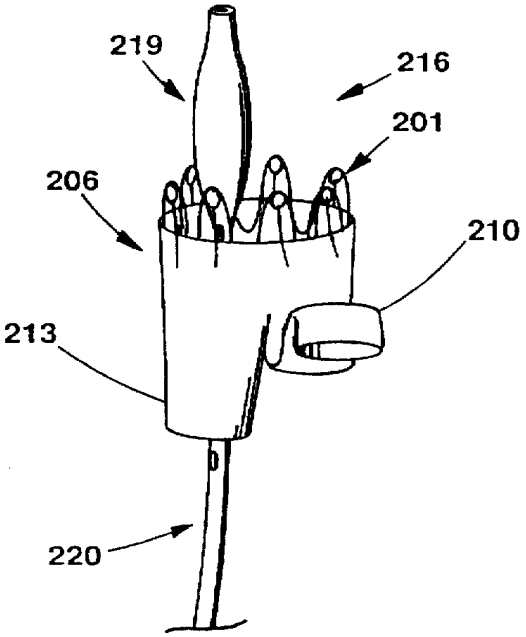


Fig. 38

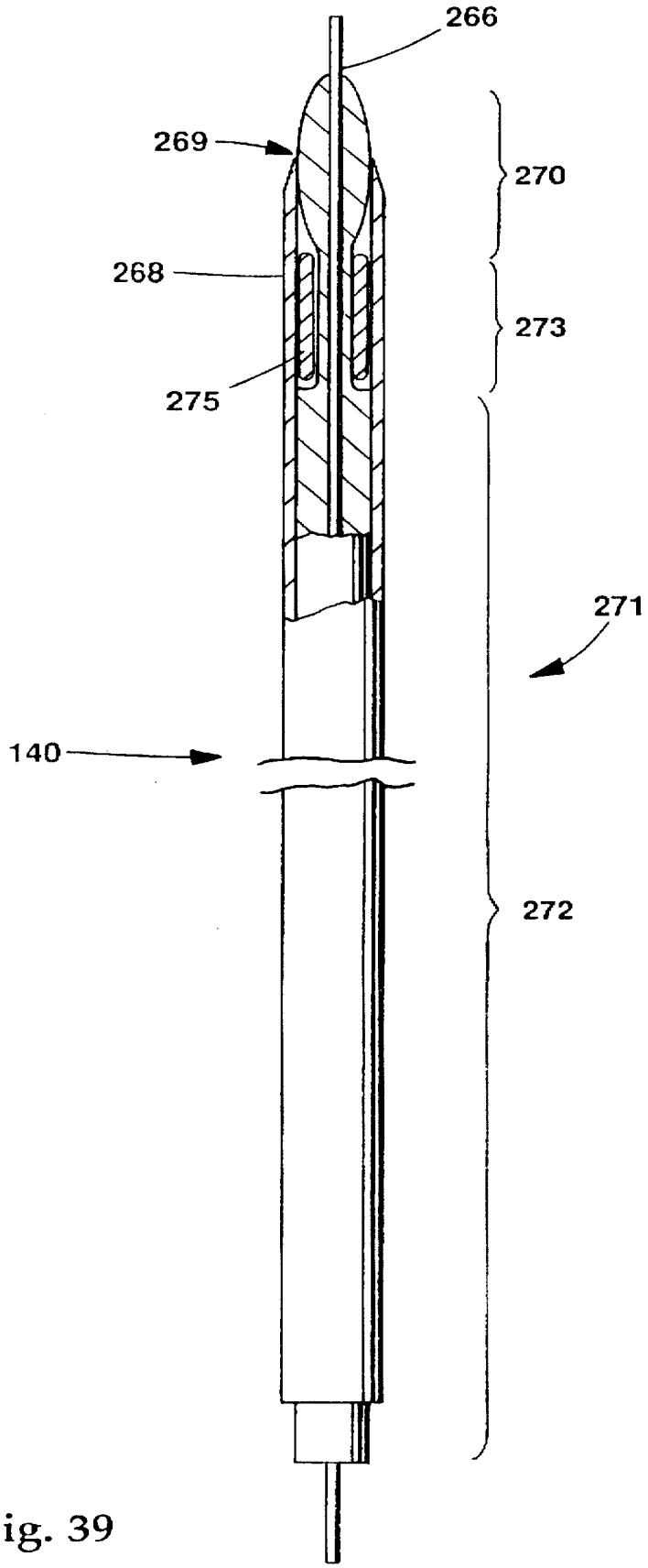


Fig. 39

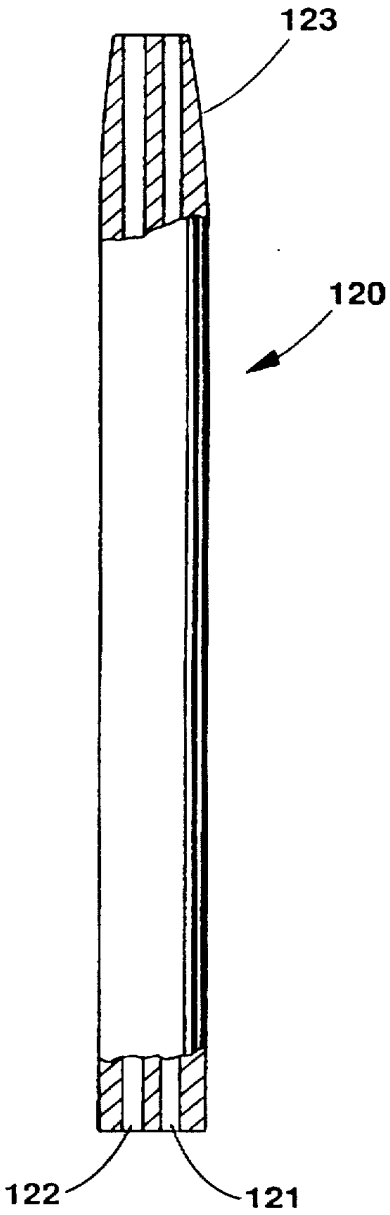


Fig. 42

Fig. 40

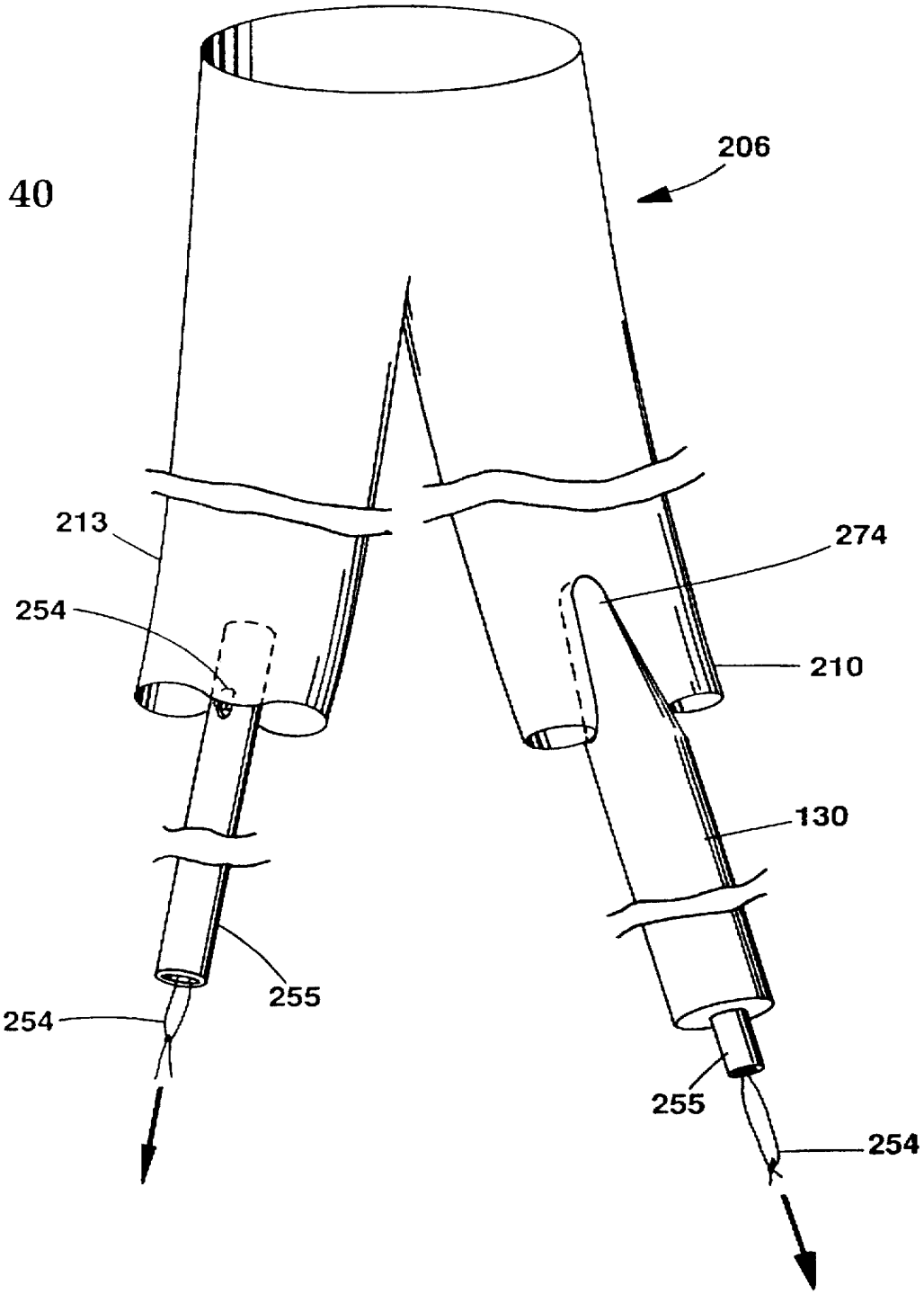
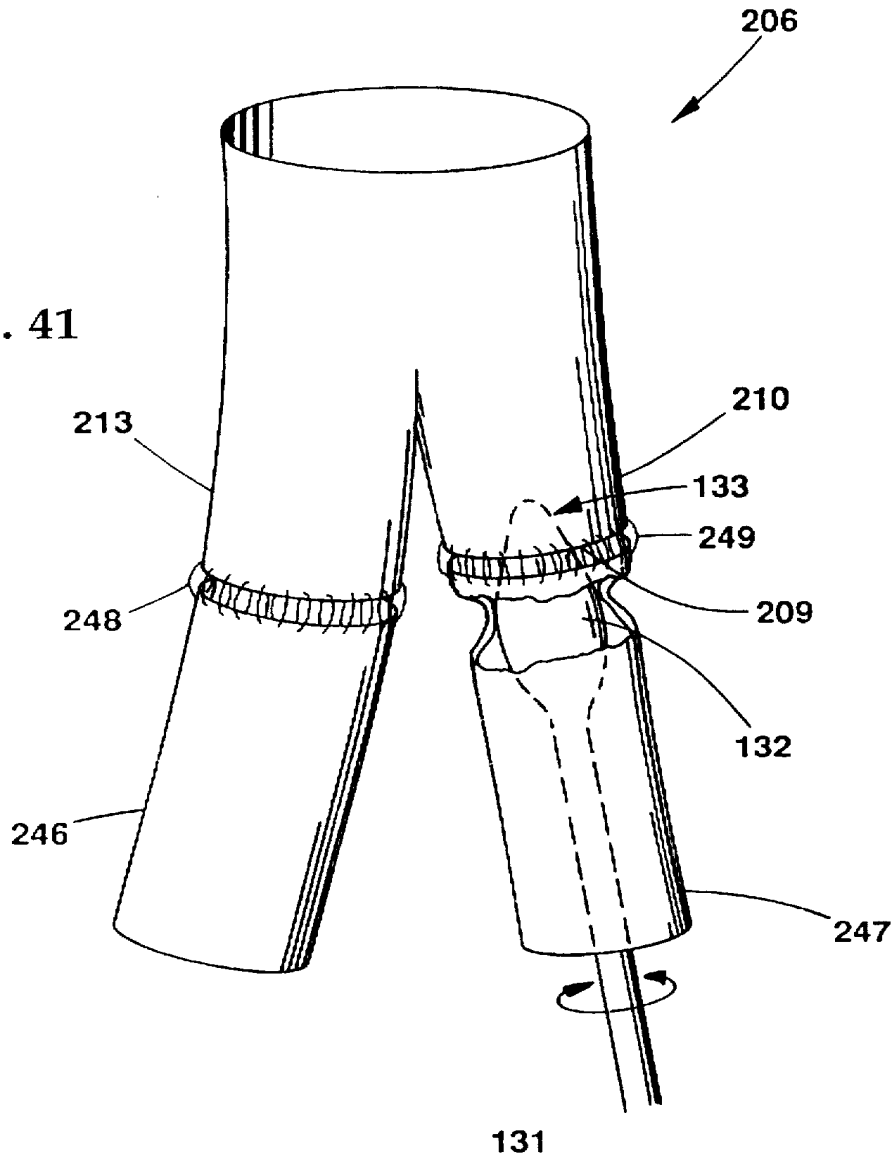


Fig. 41



EXPANDABLE TRANSLUMINAL GRAFT PROSTHESIS FOR REPAIR OF ANEURYSM

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation of application Ser. No. 08/173,148 for an Expandable Transluminal Graft Prosthesis for Repair of Aneurysm and Method for Implanting, filed Dec. 22, 1993, now U.S. Pat. No. 5,562,726, which is a continuation-in-part of application Ser. No. 07/868,792 for an Expandable Transluminal Graft Prosthesis for Repair of Aneurysm and Method for Implanting, filed Apr. 15, 1992, now abandoned, which is a continuation-in-part of Ser. No. 07/782,696 for an Expandable Transluminal Graft Prosthesis for Repair of Aneurysm and Method for Implanting, filed Oct. 25, 1991, now abandoned.

TECHNICAL FIELD

The invention relates to transluminal graft prostheses for the repair of aneurysms and a method for implanting them.

BACKGROUND OF THE INVENTION

The abdominal aorta is prone to aneurysmal dilation between the renal and iliac arteries. The attenuated wall of the aneurysm is unable to withstand arterial pressures so that dilation tends to progress to a point where rupture is likely. The highly invasive procedure necessary for conventional repair of an aortic aneurysm consists of an abdominal incision, dissection of the arteries, and the interruption of blood flow to the lower body and legs while an artificial graft is implanted to bypass the aneurysm.

Such invasive surgical repair of vital lumens has profound undesirable effects on the respiratory and cardiovascular systems of elderly patients who typically require the operation. The operation is expensive and entails significant life threatening risk. It is therefore highly desirable to replace conventional surgical repair with a less traumatic, less complicated and safer procedure. The present invention serves these needs, and is particularly well adapted to reconstruction of an abdominal aortic aneurysm. The prosthetic graft of this invention will provide a resilient conduit, bridging the aneurysm and reducing the risk of rupture, without the attendant morbidity and expense of conventional surgical repair. The invention, however, is not limited to aortic aneurysm repair and has applications in a variety of situations in which corporeal lumen repair is required.

There are several devices already existing which are stated to be useful for the remote repair of corporeal lumens. U.S. Pat. No. 4,512,338, issued to Balko et al., discloses a device for transluminal repair of, and restoring patency of, a weakened or damaged corporeal vessel. The device consists of a nitinol wire, previously memory-shaped into a longitudinal coil, which is cooled and reformed into a straight wire and inserted into the vessel requiring repair. When placed in the body and stripped of heat insulating means, the wire warms and returns to its preselected coiled dimensions to support the vessel wall. Use of a device such as nitinol wire may be undesirable because there is a danger of possibly puncturing or lacerating the lumen wall during the emplacement process. Another problem lies in fitting the prostheses to the vessel because the prosthesis does not assume its final shape (and length) until it is inside the artery. The exact position of both ends of the prostheses is very important due to the proximity of vital arteries to the ends of the aneurysm. Yet another problem with these devices is the difficult task of attaching the sleeve to the wire support because the wire is many times longer than the sleeve at the time it is inserted.

U.S. Pat. No. 4,140,126, issued to Choudhury, discloses a device for repairing an aneurysm. The device is mounted on the outside of a carrier catheter, and is positioned in the vessel in a collapsed form, smaller in diameter than that of the vessel. The device is then expanded onto the vessel wall by means of a mechanical expanding apparatus which is controlled by the user from outside the body by means of a wire. Upon expansion, anchoring pins are driven into the vessel wall. The wire is positioned on the outside of the carrier catheter, and is held in place by passing through many slip rings, each of which is firmly attached to the catheter. The slip rings permit the wire to slide when remotely operated. The wire is also attached to the expanding means at its proximal (downstream) end by slip couplings which permit the wire and expansion means to pass through the couplings during the expansion process. This device is mechanically complex and may not apply sufficient force to drive the pins into an atherosclerotic aorta or seal the graft to the arterial lumen. Furthermore, there is nothing to shield the vessel wall from the sharp pins while the device is moving from the insertion point to the point of repair. The pins are interspaced in folds of the graft material and could protrude from these folds while the device is moved into position. This could result in damage to the vessel wall in locations remote from the repair.

U.S. Pat. No. 4,787,899, issued to Lazarus, describes a system of positioning a graft within a body lumen. The graft is loaded into a guide which is inserted into the lumen. An inflatable balloon is used to anchor the distal (upstream) end of the graft onto the wall of the lumen, and then the guide is pushed upstream, pulling the folded graft out of the guide and onto the wall of the lumen, where staples at the proximal (downstream) end anchor into the wall of the lumen. Because the graft is folded or crimped axially, there is no sure method of determining where the expanded graft will position itself on the wall of the lumen, other than by measuring from the point of initial contact on the wall. This is difficult to do utilizing the remote insertion procedure. Also, the balloon providing the anchor for the distal (upstream) end of the graft while the guide is moved upstream may not provide enough pressure on the wall of the vessel to prevent slippage which could result in misplacement of the graft. The axial crimping used in these grafts may not impart radial elasticity and standard graft materials may not have sufficient elasticity as an intrinsic property. The small amount of apparent elasticity present in knitted grafts is actually a form of deformability in that expansion in one direction is accompanied by contraction in another. This means that the "guide" should be very close in size to the lumen of the vessel. As such, it should be introduced directly into the vessel to be repaired, rather than via a distant (much smaller) vessel. Also, the large guide may be difficult to withdraw through the graft after placement since it presents an open edge which might catch on any irregularities of the lumen.

The report, *Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study*, from the Department of Diagnostic Radiology, University of Texas M.D. Anderson Cancer Center, printed in 170 Radiology 1033–37 (1989), deals with a self-expanding graft consisting of several stents connected in a chain. Two stainless steel struts run down the length of the chain, forming a rigid structure along the longitudinal axis. The structure is partially covered in a secured nylon sheath, is compressed radially, and is

introduced into a lumen via a catheter and a blunt-tipped introducer wire used to push the graft up the catheter and into position. Placement is secured by withdrawing the catheter while holding the introducer wire stationary. This device may be difficult to insert because a chain structure is difficult to push unless it is rigid. The rigidity would make it very difficult to negotiate femoral and iliac arteries which are frequently tortuous. Precise positioning of the graft could be impaired because the pusher wire is not attached to the graft. This poses the potential for mispositioning of the graft during the withdrawal of the sheath. Hemorrhage could also be a major problem with this method of introduction. The introducer sheath is carried into position on the outside of a dilator, which must be removed before the graft can be inserted, leaving the sheath as a conduit from the artery to the outside of the body. The need to introduce the graft complicates the use of hemostatic seals on the sheath. Only one of these grafts carried barbs. The other model showed a tendency to migrate. There is a possibility that the sheathed wall of the barbed device could be breached by the barbs during transfer of the graft to the point of repair because the graft is pushed though the entire length of the catheter with the springs expanded against the inner wall of the catheter. Also, the wide mesh of the material used may not form a barrier to blood leaks, so that the aneurysm could be exposed to arterial pressure.

Endovascular repair of abdominal aortic aneurysm avoids much of the morbidity and mortality associated with conventional surgery. Most patients with abdominal aortic aneurysm lack a segment of non-dilated aorta suitable for attachment of the down stream (caudal) end of a straight (single-lumen) endovascular graft. In these patients a more secure outflow is provided by attaching the two caudal ends of a bifurcated graft to the iliac arteries.

The caudal ends of bifurcated grafts cannot extend to the sites of arterial access in the groin without impairing internal iliac arterial flow, which is an important source of spinal and colonic perfusion after aortic aneurysm repair. Therefore, direct control of the caudal ends of bifurcated grafts is not possible, resulting in a tendency to kinking, twisting and displacement, all of which have complicated previous attempts to apply this approach. The devices and techniques described below provide a means of accurate, hemostatic and permanent insertion of a bifurcated graft, with provision for the prevention of correction of these potential complications.

SUMMARY OF THE INVENTION

The present invention provides a transluminal graft prosthesis that can be safely and precisely positioned.

An object of the present invention is to provide a prosthesis for the safe repair of aneurysms without the risks associated with invasive surgical repair.

It is another object of the invention to provide a coupling between a plurality of spring expanding assemblies that provides a relatively flexible prosthesis during insertion, a relatively rigid prosthesis after attachment, and also maintains the alignment of the springs when the prosthesis is compressed by an extrusion device applied to one end.

The present invention provides a device for transluminal grafting of a prosthesis in a lumen, comprising: a tubular introducer sheath having a longitudinal bore; a prosthesis comprising a tubular graft having a longitudinal bore and disposed in the longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that it substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of the prosthesis during removal of the introducer sheath, the central control means disposed in the longitudinal bore of the tubular carrier means; and mooring loops engaging the prosthesis and passing through the apertures in the tubular carrier means to engage the central control means.

The present invention also provides a method for engrafting a prosthesis in a lumen comprising the steps of a) providing an access to the lumen; b) providing a device for engrafting the prosthesis comprising: a tubular introducer sheath having a longitudinal bore; a tubular graft having a longitudinal bore and disposed in the longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that the graft substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of the prosthesis during removal of the introducer sheath, the central control means disposed in the longitudinal bore of the tubular carrier means; mooring loops engaging the prosthesis and passing through the apertures in the tubular carrier means to engage the central control means; c) inserting the device and urging the device into a lumen to a desired location within the lumen; d) withdrawing the tubular introducer sheath to expose the graft; e) disengaging the central control means from the mooring loops; and f) removing the tubular introducer sheath, carrier means, and central control means.

The present invention provides an occlusive umbrella comprising: a spring expanding assembly having a proximal and a distal end; barbs attached to the proximal end of the spring means; a tubular graft having a longitudinal bore and having a proximal end and a distal end, the tubular graft open at the proximal end and closed at the distal end, the graft attached to the spring; a dilator having a distal end and a proximal end, the proximal end of the dilator attached to the distal end of the tubular graft; a first tubular catheter having a proximal end, a distal end, and a longitudinal bore, the first tubular catheter inserted into the longitudinal bore of the graft and attached to the proximal end of the dilator; a second tubular catheter having a proximal end, a distal end, and a longitudinal bore, the distal end of the second catheter communicating with the proximal end of the first catheter; a flexible rod having a proximal end and a distal end, the distal end of the flexible rod inserted into the longitudinal opening of the first catheter and the longitudinal opening of the second catheter, the distal end of the flexible rod contacting the dilator head.

The present invention provides a flexible spring alignment and compression resistance assembly comprising: a first and second spring expanding assembly each having a plurality of apertures; a plurality of retaining shafts each having a first end and a second end, the shafts having a diameter equal to

or smaller than the apertures of the first and second spring expanding assemblies, the first end of each of the retaining shafts slidably inserted into one of the apertures of the first spring expanding assembly and the second end of each of the retaining shafts slidably inserted into one of the apertures of the second spring expanding assembly, a first protrusion attached to each of said first ends and a second protrusion attached to each of said second ends, the protrusions larger than the apertures of the first and the second spring expanding assemblies to prevent the protrusions from passing through the apertures.

The present invention also provides a flexible spring alignment and compression resistance assembly comprising: a first spring expanding assembly having a plurality of apertures; a second spring expanding assembly; a plurality of retaining shafts each having a first end and a second end, the shafts having a diameter equal to or smaller than the apertures of the first spring expanding assembly, the first end of each of the retaining shafts slidably inserted into one of the apertures of the first spring expanding assembly and the second end of each of the retaining shafts attached to the second spring expanding assembly, a protrusion attached to each of said first ends, the protrusions larger than the apertures in the first spring expanding assembly to prevent the protrusions from passing through the apertures.

The foregoing problems are solved and a technical advance is achieved in an illustrative prosthesis for repairing an aneurysm. The prosthesis comprises a bifurcated endovascular graft having a main body and first and second limbs extending therefrom. The main body includes a main bore extending longitudinally therein and having a cranial orifice. The first limb includes a first bore extending longitudinally therein, communicating with the main bore, and having a first caudal orifice. The second limb includes a second bore extending longitudinally therein, communicating with the main bore and having a second caudal orifice. The prosthesis also comprises a first imageable marker extending longitudinally along the first limb and a second imageable marker extending longitudinally along the first limb and spaced at least a predetermined distance away from the first marker.

The invention also comprises an illustrative prosthesis delivery system for percutaneously inserting the prosthesis in an aneurysm. The delivery system comprises a tubular introducer sheath having a sheath bore extending longitudinally therein and a central carrier coaxially positionable within the sheath bore of the sheath. The central carrier includes a head region having a dimension approximating said sheath bore, a shaft region having a dimension approximating the sheath bore, and a stem region positioned between the head and shaft regions and having a dimension smaller than the sheath bore for positioning the prosthesis therearound and in the sheath bore.

The present invention also includes an illustrative method of inserting a bifurcated prosthesis in an aneurysm utilizing the prosthesis delivery system. The method comprises the steps of percutaneously obtaining cross access with a first guide between femoral arteries positioned caudal to the aneurysm; percutaneously obtaining access to a lumen of the aneurysm with the second guide; and positioning the prosthesis in the aneurysm and one limb thereof in one of the femoral arteries with the prosthesis delivery system and the second guide. The method also comprises the steps of positioning another limb of the prosthesis in the other of the femoral arteries with the first guide and releasing the prosthesis from the delivery system when the prosthesis is positioned in the aneurysm.

The invention is described in greater detail below based on a few selected embodiments. Those skilled in the art will appreciate that the prosthesis according to the invention can be applied in various modifications.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side view of a tubular graft of the instant invention;

FIG. **2** is a side view of a spring expanding assembly of the instant invention;

FIG. **3** is a top cross-sectional view of a spring expanding assembly shown in FIG. **2** taken along A—A;

FIG. **4** is a top cross-sectional view of a spring expanding assembly shown in FIG. **2** taken along B—B;

FIG. **5**A–C are side view of alternative elbows of the spring expanding assembly of the instant invention;

FIG. **6** shows a spring expanding assembly (with a barb attached) sutured to the graft;

FIG. **7** is a side view of a flexible spring alignment and compression resistance assembly;

FIG. **8** shows the elbow and retaining bar of the flexible spring alignment and compression resistance assembly of FIG. **7**;

FIG. **9**-A is a longitudinal cross-sectional view of two compressed spring expanding assemblies connected by the flexible spring alignment and compression resistance assembly of FIG. **7**;

FIG. **9**-B is a longitudinal cross-sectional view of two uncompressed spring expanding assemblies connected by the flexible spring alignment and compression resistance assembly of FIG. **7**.

FIG. **10** is a side-view of a flexible spring alignment and compression resistance assembly and shows the retaining bar rigidly attached to one of the spring expanding assemblies;

FIG. **11** is a longitudinal cross-sectional view of a tubular carrier of the instant invention shown with a dilator head at the distal (upstream) end;

FIG. **12** is a longitudinal cross-sectional view of a "muzzle loading" apparatus of the instant invention;

FIG. **13** is a longitudinal cross-sectional view of the proximal (downstream) end of the introducer sheath;

FIG. **14** is a longitudinal cross-sectional view of the aorta and iliac arteries and shows a dilator head, introducer sheath, tubular carrier, arteriotomy, and central control means;

FIG. **15** is a longitudinal cross-sectional view of the aorta and iliac arteries and shows a graft implanted in the aorta on either side of an aneurysm;

FIGS. **16** and **17** are longitudinal cross-sectional views of an apertured tubular carrier showing mooring loops and central control means;

FIG. **18** is a longitudinal cross-sectional view of an alternative means of graft attachment;

FIG. **19** is a longitudinal cross-sectional view of an occlusive umbrella; and

FIG. **20** is a longitudinal cross-sectional view of the aorta and the iliac arteries showing the use of a graft in conjunction with an occlusive umbrella and a femoro-femoral graft.

FIG. **21** depicts a segment of a self-expanding stent;

FIG. **22** depicts a bifurcated graft;

FIG. **23** depicts a carrier of the present invention;

FIGS. **24** and **25** depict alternative embodiments of a sheath with a tapered cranial external surface;

FIGS. **26** and **27** depict a carrier of the present invention;

FIG. **28** depicts tubular extensions sutured to a graft of the present invention;

FIG. **29** depicts an alternative mechanism for attaching the tubular extensions to a graft of the present invention;

FIG. **30** depicts a single loop of suture material for applying traction to a caudal limb of the present invention;

FIG. **31** depicts attachment to multiple points on a caudal limb of the present invention;

FIGS. **32** and **33** depict catheter side ports for allowing traction to be applied at multiple points;

FIG. **34** depicts tension transmitted through a short suture;

FIGS. **35** and **36** depict a caudal limb control catheter of the caudal limb control system of the present invention;

FIG. **37** depicts a suture encircling a catheter of the contralateral lumen access guidance system;

FIG. **38** depicts access to the ipsilateral limb lumen by an insertion delivery wire;

FIG. **39** depicts a distal stent insertion device of the present invention;

FIG. **40** depicts a contralateral limb straightening device;

FIG. **41** depicts an alternative limb straightening device; and

FIG. **42** is a sectioned view of a twist-preventing, double lumen catheter.

DETAILED DESCRIPTION

The graft **1** shown in FIG. **1** is in the form of an elongated cylindrical tube defining a longitudinal bore that is multiply crimped **3**, or folded over to facilitate the compression and expansion of the graft as the diameter **5** of the graft decreases and increases. Transverse elasticity may also be achieved or enhanced through inherent properties of either the weave or constituent fibers used to construct the graft **1**. The graft **1** is preferably constructed from a material such as woven multifilament polyester (such as Dacron™), which is known to be sufficiently biologically inert, non-biodegradable, and durable to permit safe insertion inside the human body. Any material with such qualities may be used, however. Polyester is also known to excite fibrous ingrowth which will secure the graft **1** to the wall of the lumen within a few months of its insertion.

The typical graft **1** is of fixed length and relatively inelastic along its longitudinal axis. A variable length graft may also be used and could be constructed by either having two pieces of graft, one inserted within the other in a telescopic arrangement, capable of being manipulated within the body, or having one continuous piece of material that is folded back on itself. A spring within this area of the graft ensures apposition of the various layers at this level; the outer layers having a slightly smaller maximum diameter to provide a buttress against which the spring can expand in the absence of a secure arterial wall. Variability of length may also be achieved by providing elasticity along the longitudinal axis of the graft as a property of graft material or by having one or more elastic sections of such material within the main body of the graft.

The spring assembly **6** of FIG. **2** includes arms **15** which are bent to form elbows **7**. Surgical barbs **10** having sharp tips **13** are attached to the arms **15** and protrude from the elbows **7**. FIG. **3** is a top cross-sectional view of the spring assembly **6** of FIG. **2** taken along A—A showing six elbows **7** and associated barbs **10**. FIG. **4** is a top cross-sectional view of the spring assembly **6** taken along B—B showing twelve arms **15** which extend from the six elbows **7** shown in FIGS. **2** and **3**. A spring assembly **6** is typically formed from a continuous piece of fine gauge stainless steel spring wire that, if opened out, would appear in the shape of a zig-zag with multiple elbows **7**. FIG. **5**A–C show that these elbows **7** may be simple arches **7**, recurved arches **42**, or apertured **60** respectively. The advantage of simple arches **7** is that the spring assembly **6** expands the longitudinal aperture of the graft **1** more evenly. The advantage of the recurved arches **42** is that they collapse more readily and are more durable. The apertured elbows **60** are used in the flexible spring alignment and compression resistance assembly. The two ends of the piece of bent wire are permanently attached end-to-end so as to form a circular structure, e.g., FIGS. **2**, **3** and **4**. FIG. **6** shows a portion of the spring assembly **6** with a barb **10** attached to an arm **15** of the spring assembly **6**. The spring assembly **6** is sutured to the graft **1** with a non-biodegradable thread **36**. The spring assembly **6** may also be constructed out of other inert metals such as titanium, or a plastic. When expanded, the spring assembly **6** is circular in shape when viewed from above, and may have a diameter, when in a relaxed state, equal to approximately twice the diameter of a lumen into which the graft **1** is to be inserted. The spring assembly **6** is typically attached to the inside of the cylindrical graft **1** at the distal (upstream) end or both ends of the graft **1** by sutures **36** of non-biodegradable material. The sutures **36** attach to the spring assembly **6** in such a way that the majority of the spring assembly **6** is covered by the graft material **1**. Other embodiments may incorporate spring assemblies **6** being attached to the outside of the tubular graft **1** which would present a smoother surface to the flowing blood but has the drawback that the graft **1** would be in less intimate contact with the wall of the lumen.

The spring assembly **6** on the distal (upstream) end of the graft **1** has small surgical barbs **10** firmly attached to the spring assembly **6**. The spring assembly **6** at the proximal (downstream) end of the graft may also be provided with barbs. The attachment of the barbs **10** to the graft or spring assembly **6** must be permanent and can be either welded, brazed, or coupled in a fashion that is both biologically acceptable, and yet strong enough to withstand long-term stress. These barbs **10** spread radially outward from the longitudinal axis of the graft **1**, such that when the spring assembly **6** opens inside the lumen, the barb tips **13** will come into contact with and engage the wall of the blood vessel to be repaired. The barb tips **13** will become imbedded in the wall through both the driving action of the spring assembly **6** and the pressure created by the flow of blood through the graft **1**. The barb tips **13** are sharp and may be curved slightly downward toward the graft **1** to provide a more secure anchor in the direction of blood flow. The barbs **10** are positioned so that they are further upstream than the elbows **7** of the distal (upstream) spring assembly **12**, and are of such a size that the wall of the blood vessel is not punctured or pierced when the barb tips **13** are firmly embedded therein. Attaching the barbs **10** to the spring assembly **6** via shafts bonded to the spring assembly **6** at the middle of one of the two arms **15** extending from an elbow **7** of the spring assembly **6** permits the barb tip **13** to slightly retract or rotate when compressed for loading into the introducer sheath **4** (as best seen in FIG. **6**).

Though the spring assembly **6** is typically sutured only to the ends of the graft **1**, several such spring assemblies **6** may also be connected to one another for added strength. This is necessary in embodiments of the prosthesis that require the graft to resist compression during removal from the introducer **4**. Some flexibility is retained by connecting the spring

assemblies **6** to each other in a way that permits separation (but not overlapping or misalignment) of adjacent spring elbows **60**. FIG. **7** illustrates such a flexible spring alignment and compression resistance assembly **49** and shows a first spring arm **50** and a second spring arm **52** connected via a retaining bar **54**. The retaining bar **54** is constructed of fine gauge wire with a protrusion **56** at each end. FIG. **8** shows a modified elbow **60** and includes an aperture **58** provided to receive the retaining bar **54**. The retaining bar **54** slides through apertures **58** provided in the modified elbows **60** of adjacent arms **50** and **52**. The rigidity of the retaining bar **54** prevents overlapping during compressive loading of the prosthesis, while the protrusions **56** prevent disassociation of the joints during flexion of the graft which might otherwise disrupt the chain of springs **50** and **52**. The shaft **62** of the retaining bar **54** has a diameter slightly smaller than aperture **58** and the protrusion **56** has a diameter slightly larger than the aperture **58**. The slidably mounted retaining bars **54** allow arms **52** and **54** to separate but prevent arms **52** and **54** from sliding over one another.

It is desirable that the joint between the spring assemblies **6** be flexible during the introduction and relatively rigid once the graft has been implanted. As shown in FIGS. **9**-A and **9**-B, the joint is more flexible when the spring assemblies **64** and **66** are compressed (i.e., during insertion) and relatively rigid when the spring assemblies **64** and **66** are in an uncompressed state (i.e., after implantation). FIGS. **9**-A and **9**-B show a first spring assembly **64** connected to a second spring assembly **66** by a flexible spring alignment and compression resistance assembly **49**. FIG. **9**-A shows the spring assemblies **64** and **66** in a compressed state and FIG. **9**-B shows the spring assemblies **64** and **66** in an uncompressed state. Angle α represents the maximum angle between spring assemblies **64** and **66** when the springs are in a compressed state and angle βrepresents the maximum angle between spring assemblies **64** and **66** when the springs are in an uncompressed state. Thus, the angle between spring assemblies **64** and **66** decreases with an increase in the transverse diameter of spring assemblies **64** and **66**. The angle of flexion will be largest when spring expanding assemblies **64** and **66** are in a compressed state (diameter d_1) and the angle of flexion will be smallest when spring expanding assemblies **64** and **66** are in an uncompressed state (diameter d_2) . Thus, because α is larger than β, the prosthesis becomes more rigid as its diameter increases. During insertion, the graft **1** is confined within the introducer sheath **4** and remains both narrow and flexible. After removal from the sheath **4** the graft **1** expands becoming more rigid.

The retaining bar **54** may also be non-slidably attached at one (but not both) of its ends to one of the spring expanding assemblies **51** as shown in FIG. **10**.

FIG. **11** shows a tubular carrier **21** which has a dilator head **22** mounted at the distal (upstream) end. The dilator head **22** may have a distal (upstream) conical portion **75** and a proximal (downstream) cylindrical portion **74**. The dilator head **22** may have a soft tipped guide-wire **68** protruding from its distal (upstream) end. The cylindrical portion **74** of the dilator **22** has a diameter d equal to the internal diameter of the introducer sheath **4**.

FIG. **12** shows the assembled "muzzle loading" apparatus and includes a tubular carrier **21** with a dilator head **22** at the distal (upstream) end; dilator head lip **27**; introducer sheath **4**; graft **1** which is slid onto the tubular carrier **21**; distal (upstream) spring assembly **12**; proximal (downstream) spring assembly **31**; central control means **26** which is inserted into the tubular carrier **21**; distal (upstream) end **8** of the graft **1**; proximal (downstream) **9** end of the graft **1**; and non-biodegradable sutures **36** that permanently attach the spring assemblies **12** and **31** to the graft **1**. If the outer diameter of the tubular carrier **21** is equal to the internal diameter of the introducer sheath **4**, leakage of blood between the two is minimal. Alternatively, the introducer sheath **4** may be closed at its proximal (downstream) end by a small rubber seal **70** as shown in FIG. **13** which has an aperture **72** for receiving the carrier **21**.

"Muzzle loading" involves inserting the graft **1**, already mounted on the tubular carrier **21**, into the distal (upstream) end of the introducer sheath **4** before insertion of the introducer sheath **4** into the lumen. "Breech loading" involves inserting the graft **1** into the introducer sheath **4** from the proximal (downstream) end of the sheath **4**, after the introducer sheath **4** has been inserted into the patient and is in position.

37 Muzzle loading" has two main advantages that make it the preferred means of operation. The first advantage of "muzzle loading" over "breech loading" is the lower probability of hemorrhage. In the "breech loading" technique, the dilator **22** must be removed before the graft **1** can be inserted, leaving the introducer sheath **4** as a large conduit between the arterial circulation and the outside of the body. Any effective seal in the introducer sheath **4** will obstruct insertion of the graft **1** unless this is carried within a second sheath (with the consequent increase in size). The only other way to control the hemorrhage is to clamp the introducer sheath **4** on the outside, however, clamping is unlikely to be totally occlusive and may damage the introducer sheath **4**. Moreover, the clamp must be removed to allow passage of the graft **1** which produces another period of rapid hemorrhage.

The second advantage of "muzzle loading" over "breech loading" is that if a single sheath **4** is to be used in the "breech loading" technique, the graft **1** must be placed within the introducer **4** at the time of operation. This can be a tricky procedure, especially when the outer end of the introducer sheath **4** is issuing a continual stream of blood.

FIG. **14** shows the common femoral artery **30**; proximal (downstream) end **19** of the introducer sheath **4**; tubular carrier **21**; iliac artery **34**; aorta **2**; aortic aneurism **20**; dilator head **22**; and central control means **26**. FIG. **15** shows the graft **1** implanted in the aorta **2** at the site of the aortic aneurysm **20**.

In the "muzzle loading" technique the graft **1** is inserted into the distal (upstream) end of the introducer sheath **4**. The introducer sheath **4** is thin walled, smooth, flexible, sterilizable, non-toxic, and is tubular in form. The tubular carrier **21** fits inside the introducer sheath **4**. A close match between the sizes of the sheath **4** and carrier **21** helps to eliminate any buckling of the tubular carrier **21** within the sheath **4** while simultaneously limiting the seepage of blood between the carrier **21** and the sheath **4**. The tubular carrier **21** has a dilator **22** attached to the distal (upstream) end which has a conical tip **75** to facilitate the atraumatic passage of the apparatus from the groin into the upper end of the aneurysm. The dilator **22** is also provided with a cylindrical portion **74** on its proximal (downstream) end which mates with the introducer sheath **4**.

The introducer sheath **4** fits over the cylindrical portion **74** of the dilator head **22**. A tiny lip **27** at the junction between cylindrical portion **74** and conical portion **75** of the dilator head **22** overlaps the end of the introducer sheath **4** so that no edges are presented to the arterial lumen (or the thrombus that lines the aneurysm) during introduction of the appara-

tus. This reduces the trauma to vessels and minimizes the chance of dislodging a piece of thrombus that could embolize into the kidneys or lower limbs.

The central control means **26** may take the form of a catheter which extends the entire length of the carrier to the tip of the dilator head **22** so that its lumen can be used for the injection of angiographic dye or as a means of threading the apparatus over a previously placed guide wire. Alternatively, the central control means **26** may pass all the way through the dilator head **22** and slide back and forth within the carrier **4** so that it may function as a guide wire itself. This has been found to be useful in the technique of percutaneous insertion.

In the "breech loading" device, the introducer sheath **4** is a tubular structure having a uniform-diameter and is made of the same material as the "muzzle loading" introducer sheath **4**. With this design, the tubular carrier **21** does not have a dilator **22** because the introducer sheath **4** can be carried into position around a standard dilator, which would then be removed before insertion of the tubular carrier **21** with the graft **1**.

FIG. **16** shows the tubular carrier **21**; mooring loops **39**; central control wire **15**; and apertures **29**, **29'**, **101**, and **101'** in the wall of tubular carrier **21**.

FIG. **17** shows the tubular carrier **21**; mooring loops **39** and **39'**; apertures **29**, **29'**, **101** and **101'** in the wall of the tubular carrier **21**; and central control thread **25**.

All "muzzle loading" (and some "breech loading") devices use a central control means **26** that runs up the center of the tubular carrier **21**, to which the graft **6** may be moored, and which is used for maintaining the axial position of the graft **1** during removal of the introducer sheath **4**. This central control means **26** can take one of several forms, including a flexible shaft **115** (such as a stainless steel wire or a narrow catheter) (as shown in FIG. **16**) or a simple thread **25** (as shown in FIG. **17**) that passes up the center of the tubular carrier **21**, through the mooring loops **39** and **39'**, and then doubles back through the center of the tubular carrier **21** to its point of origin outside the patient. In the absence of mooring loops **39** and **39'**, this thread **25** can exit an aperture (**29**, **29'**, **101** and **101'**), pass through an elbow **7** of the spring assembly **6**, traverse the apertures to the opposite elbow **7** of the spring assembly **6** (which it also encircles), pass back into the lumen of the carrier **21** through an aperture (**29**, **29'**, **101**, and **101'**) and thereby return to the proximal end of the catheter **21**. Release of the mooring loops **39** and **39'** is accomplished by withdrawing the central control shaft **115** from the tubular carrier **21** or by releasing one end of the central control thread **25**, which is then removed from the tubular carrier **21**. If each end of the graft **1** is desired to be controlled and positioned independently of the other, the central control shaft **115** can be partially withdrawn to a point in between the two sets of mooring loops **39** and **39'**. If the central control means **26** is a central control thread **25** (instead of a flexible shaft **115**), multiple threads **25** can be used, one for each set of mooring loops **39** and **39'**.

Because it has no dilator head, the carrier of the "breech loading" device need not traverse the graft **1** to the distal (upstream) end of the introducer sheath **4**. Instead, it can end at the graft **1** which would be pushed rather than pulled from the sheath **4**. No attachment to the graft **1** would then be needed, but the graft **1** would have to be more rigid and placement would be less precisely controlled.

The "muzzle loading" method will now be described. To assemble the apparatus prior to insertion, the central control means **26** is inserted through the entire length of the tubular carrier **21**, which, in turn, is inserted through the entire length of the introducer sheath **4**. With the end of the tubular carrier **21** and central control means **26** protruding past the top of the introducer sheath **4**, the graft **1** is slid over the dilator head **22** and down the outside of the tubular carrier **21** until positioned directly below the tapered dilator head **22** of the tubular carrier **21**. As shown in FIG. **16**, the distal (upstream) end of the graft **1** is then moored around the central control means **26** with a mooring loop **39** that engages the spring assembly **6**, or is sutured to the graft **1**. The mooring loop **39** enters the tubular carrier **21** via the aperture **29** and **29'** and forms a mooring loop **39** which engages the central control means **26** so that the mooring loops **39** cannot exit the carrier **21** while the control means **26** occupies the longitudinal opening of the tubular carrier **21**. These mooring loops **39** will remain attached to the graft **1** or springs **6** after placement of the graft **1**. The mooring loops **39** are preferably made of a monofilament material of low thrombogenicity that in some applications may be biodegradable. When the central control means **26** is withdrawn, mooring loops **39** are free to exit the tubular carrier **21**. The proximal (downstream) end of the graft **1** can also be secured in the same manner through a second set of mooring loops **39'** passing through a second set of apertures **101** and **101'** in the tubular carrier **21**, thereby facilitating independent positioning of the two ends of the graft **1**. Once the graft **1** is compressed, the introducer sheath **4** is slid over the tubular carrier **21** and the edge of the introducer sheath **4** is fitted snugly against the lip **27** of the dilator head **22**. The barbs **10** on the distal (upstream) spring assembly **12** are completely covered by the introducer sheath **4**. The apparatus is now ready for insertion.

FIG. **18** is a longitudinal cross-sectional view of an alternative embodiment of the carrier catheter that does not employ a central control means and shows cantilevered hooks **100**, outer carrier **102**, inner catheter **104**, and dilator head **22**. In this embodiment, a pair of concentric catheters is bonded at the distal (upstream) end such that when the inner catheter **104** is pulled in the proximal (downstream) direction from outside the body, the outer catheter **102** bulges out. The graft **1** is held in position on the outer catheter **102** by means of cantilevered hooks **100** attached to the outer surface of the outer catheter **102**. These hooks **100** engage the spring assembly **6** of the graft **1** during insertion and prevent the graft **1** from changing its axial position while the introducer sheath **4** is withdrawn. The graft **1** is released from the hooks **100** when the outer catheter **102** is withdrawn.

These methods of securing the graft to the carrier for selective release are required because the outward expansion of the graft against the sheath generates considerable friction that must be overcome in order to extrude the graft. Without such a mechanism, the graft would move with the sheath and would be imprecisely extruded. In order to minimize the forces involved in extrusion, the sheath is constructed of a material (such as Teflon™) which has a low friction surface or is coated with a lubricous material (such as hydragel polymer).

The insertion procedure may be a surgical procedure or may be accomplished percutaneously using a guide wire. In the surgical approach, for example, the femoral artery **30** is exposed through a short groin incision. Heparin is administered intravenously, hemostatic clamps or bands are applied, and the femoral artery **30** is opened. The complete apparatus is inserted into the open femoral artery **30**, and is pushed through the femoral **30** and iliac **34** arteries into the

aorta **2**. The graft **1** is positioned so as to cover the entire length of the aortic aneurysm **20**. Positioning is confirmed through fluoroscopy and angiography. Once the positioning has been confirmed, the introducer sheath **4** is pulled back exposing the distal (upstream) barbed spring assembly **12** and part of the length of the graft **1**. The springs expand driving the barb tips **13** into the wall of the aorta **2**. Once the entire graft **1** is out of the introducer sheath **4** the central control means **26** is withdrawn. As the central control means **26** is withdrawn past the point where the graft **1** is moored to the central control means **26** via the mooring loops **39**, the mooring loops **39** will pass over the end of the central control means **26** and be free to pass through the apertures **29** and **29'** in the tubular carrier **21**. Blood flow in the aorta **2** aids in opening up the multiply crimped middle portion of the graft **1**. Placement is performed in two stages. First, the introducer sheath **4** is withdrawn to expose the distal (upstream) **8** half of the graft **1** which expands and attaches to the wall of the aorta **2**. The central control means **26** is then withdrawn to a point between the holes **29** and **29'** and **101** and **101'** in the tubular carrier **21**, leaving only the proximal (downstream) **9** end of the graft **1** attached to the carrier **21**. The proximal (downstream) **9** end of the graft **1** can then be positioned independently of the distal (upstream) **8** end of the graft **1**. The introducer sheath **4** is then withdrawn over the proximal (downstream) spring assembly **31**. When the proximal (downstream) **9** end of the graft **1** is exposed it also expands under the action of the spring assembly **31**, driving the barbs **10** (when present) into the wall of the aorta **2**. The central control means **26** can then be withdrawn past the point where the central control means **26** engages the second set of mooring loops **39'**, thereby releasing the graft **1** completely. After the proximal (downstream) spring assembly **31** has been released, the tubular carrier **21**, central control means **26**, and introducer sheath **4** are removed from the patient's body. The femoral artery **30** is then repaired and the wound closed.

Aortic aneurysms frequently encompass the entire distal aorta. In these cases, there is no normal aorta between the aneurysm and the iliac arteries. In order to provide a secure arterial wall for the attachment of the proximal (downstream) end of the graft, the graft may be placed from the infrarenal aorta, above the aneurysm, into the iliac artery on the side of insertion. Such an application also requires conventional femoro-femoral arterial bypass to restore continuity of the circulation to the contralateral limb and the insertion of an occlusive umbrella to prevent retrograde flow through the contralateral common iliac artery into the aneurysm. FIG. **19** is a longitudinal cross-sectional view of an occlusive umbrella **80**. The graft **82** is open proximally, but closed distally, forming an inverted picket **86**, which is capped by a blunt tip dilator **90**. A barbed **92** spring assembly **88** expands the open end of the graft **82**. An umbrella catheter **110** having a longitudinal bore is attached to the inside of the dilator **90** and extends through the central axis of the umbrella **80**. A pusher catheter **95** is abutted against the umbrella catheter **110** so that the longitudinal openings **111** and **112** are in alignment. A central pusher wire **93** is inserted through the longitudinal opening **112** of the pusher catheter **95** and through the longitudinal opening **111** of the umbrella catheter **110** until the central pusher wire **93** rests against the blunt tip dilator **90**.

FIG. **20** shows an aneurysm **20** that extends from the aorta **2** to an iliac artery **34**. The graft **1** is inserted so that it forms a conduit from the aorta **2** to the iliac artery **34**. A conventional femoro-femoral bypass graft **94** is used to convey blood from the side receiving the entire aortic blood flow through the proximal end of the graft to the other limb. The occlusive umbrella **80** prevents arterial blood (which enters the iliac artery **34** via the femoro-femoral bypass **94**) from "backing up" into the area between the graft **1** and the aneurysm **20**.

Prior to insertion, the occlusive umbrella **80** is squeezed into the distal (upstream) end of the introducer sheath **4**, until the introducer sheath **4** engages the blunt tip dilator **90** and the umbrella catheter **110** meets the pusher catheter **95**. The umbrella catheter **110** and the pusher catheter **95** are kept in alignment by the central pusher wire **93** inserted through longitudinal openings ill and **112**. The apparatus is introduced into the femoral artery **30** through a longitudinal arteriotomy and advanced into the common iliac artery **34**. The pusher **95** passes through the lumen of a flexible, thin walled, introducer sheath **4**. The occlusive umbrella **80** is extruded from the introducer sheath **4** by applying force to the pusher **95** and central pusher wire **93** while pulling on the introducer sheath **4**. Once the springs **88** and hooks **92** are out of the confines of the introducer sheath **4** they expand onto the arterial wall securing the umbrella **80**. The pusher catheter **95**, pusher wire **93**, and introducer sheath **4** are then withdrawn from the femoral artery **30** through the arteriotomy. The arteriotomy is then anastomosed to the distal end of the femoro-femoral bypass **94**.

When a "breech loading" introducer sheath is used, the sheath must first be inserted (over a dilator) through the femoral artery to the proximal end of the aneurysm. This can be done percutaneously or via an arteriotomy in the isolated femoral artery. The dilator is then removed, the sheath clamped, and the graft inserted. The graft is forced down the introducer sheath by a control catheter, wire or rod, which may traverse the lumen of the graft and attach the distal end of the graft to the control device or may end bluntly at the lower end of the graft. The latter requires that the graft be sufficiently rigid to withstand the compression necessary to overcome the considerable friction between the sheath and the graft.

Hereinafter described is a bifurcated endovascular graft **150** and the method of insertion thereof for repair of abdominal aortic aneurysm. Bifurcated graft insertion system **160** comprises prosthesis **170** (graft/stent combination), prosthesis delivery system **186**, distal limb control system **190**, distal stent insertion device **140**, distal limb straightening device **130**, and twist preventing catheter **120**. Many features of the introducer system and the prosthesis are to be found in the various embodiments of the tubular graft insertion system. The others are unique to the bifurcated graft.

The prosthesis comprises a graft and one or more stents. Stents occupy the lumen of the graft orifices. Stents expand the graft and fix it in position.

All stents are of the self-expanding (Gianturco) type of which a segment **201** is depicted in FIG. **21**. A complete loop of wire is bent back and forth to form a crown or wheel with recurved points **202** between straight limbs **203**. The length and number of limbs vary depending on the materials, the size of the vessel to be grafted, and the size constraints of the introducer system. However, the resting (non-deformed) diameter of a stent always exceeds the diameter of the vessels to be grafted. Cranial stents are attached to the graft. Bends, protrusions or other surface irregularities on the stents are used as a point of attachment **204**. Protrusions may take the form of catheters or wires, which may be glued, soldered, or brazed to the stent. All cranial stents bear barbs **205**. These sharp metal barbs project outward from the

surface of the stent. The barb points caudally, cranially, or in both directions. They are soldered, brazed or glued to a stent at any point. The number of barbs is variable. Caudal stents are used with and without barbs.

Depicted in FIG. **22** is bifurcated graft **206** having a cranial orifice **207** and at least two caudal orifices **208** and **209**. The graft resembles trousers. The graft includes a main body **250** and caudal limbs **210** and **213** extending therefrom. Main body **250** includes main bore **251** extending longitudinally therein and having cranial orifice **207**. Caudal limb **210** includes bore **252** extending longitudinally therein, communicating with main bore **251**, and having caudal orifice **209**. Caudal limb **213** includes bore **253** extending longitudinally therein, communicating with main bore **251**, and having caudal orifice **208**.

Grafts are knitted or woven in one piece from a durable yarn such as polyester. There are no seams. An element of elasticity may be incorporated as a property of the fabric or by subsequent treatments such as crimping. The dimensions of the graft vary according to the dimensions of the infrarenal aorta and the common iliac arteries. In each patient a graft will be selected that has diameters that exceed those of the recipient vessels.

In the majority of cases it is important to preserve blood flow through the internal iliac arteries. Therefore, most grafts will be of such a length that caudal orifices **208** and **209** lie in the common iliac arteries. An alternative embodiment uses grafts that extend through the entire common and external iliac arteries to exit the arterial tree via the femoral arteries. The caudal limb of such a graft may be perforated or constructed of very porous material to permit continued perfusion of the internal iliac artery by leakage.

Contralateral graft limb **210** on the side opposite to the side of insertion is marked with radio-opaque lines or imageable markers **211** and **212**. These lines are woven into the cloth of the graft or applied after weaving. The lines may be continuous or interrupted. These lines or markers need be only imageable with any commercially available medical imaging equipment such as x-rays, CT, MRI, or the like. The radio-opaque line is a fine wire or chain of inert metal. Alternatively, the line is incorporated into an inert paint or plastic. The ipsilateral graft limb **213** needs only at least two radio-opaque markers **214** and **215** at caudal orifice **208**.

Prosthesis delivery systems **108** comprises central carrier **216** and co-axial introducer sheath **217**. The introducer sheat has a constant diameter and wall thickness. The internal diameter of the sheath corresponds to the external diameter of the central carrier along two regions. One region is located caudally at carrier shaft **218**, and the other region is located cranially at carrier head **219**. In between these two regions is much narrower carrier stem region **220**.

The introducer sheath is a thin-walled, large-bore catheter made of flexible, inert plastic with a low coefficient of friction. The wall of the sheath incorporates mechanisms to resist kinking (such as an internal wrap of metal wire). The sheath is of constant diameter and wall thickness, except at cranial orifice **223** where external surface **221** of the sheath tapers to meet outer surface **222** of carrier head **219** in a smooth transition as depicted in the preferred and alternative embodiments of FIGS. **24** and **25**. Caudal end **224** of the sheath as depicted in FIG. **26** includes a hemostatic seal **225**, which engages outer surface **226** of the carrier shaft **218**. The seal incorporates a well-known lock **227** to grip the carrier shaft **226** tightly during introduction and prevent premature exposure of prosthesis **228**. The length of the sheath depends on the length of the central carrier. The sheath must cover the entire carrier stem and overlap portions of the carrier head and the carrier shaft.

As depicted in FIGS. **26** and **27**, central carrier **216** includes inner catheter **229** and a co-axial outer catheter **230**. The inner catheter is of constant diameter and wall thickness. Caudal end **231** of the inner catheter has an injection port **232**. Outer catheter **230** has a more complicated construction. Internal lumen **233** matches the outer diameter of inner catheter **229**, but the outer diameter of the outer catheter varies. Distally, the outer diameter corresponds to the inner diameter of the introducer sheath as depicted in the embodiment of FIG. **24**. This segment of the outer cathet is carrier head **219**. Another small dilation **234** as depicted in FIG. **25** is immediately distal to the end of introducer sheath **217**, to further enhance the smooth transition from carrier head **219** to sheath **217**.

The internal diameter of the introducer sheath about the caudal end thereof also matches the external diameter of the caudal segment of carrier shaft **218**. The narrower segment of the central carrier between carrier head **219** and carrier shaft **218** is carrier stem **220**. During insertion, prosthesis **228** and its associated catheter systems are compressed into the space between introducer sheath **217** and carrier stem **220**.

As depicted in FIG. **23**, two pairs of holes **235** and **236** traverse the outer catheter of the carrier stem, one pair at each end of prosthesis **228**. As depicted in FIG. **27**, small loops of suture **237** and **238** wind around inner catheter **229** at this point, entering and exiting the lumen of outer catheter **230** through the holes. These sutures, as well as suture loops **239** and **240**, also traverse some part of prosthesis **228**, thereby attaching both ends of the prosthesis to the central carrier. Loops **237–240** (and the prosthesis) are released by removal of inner catheter **229**. It is important that the two loops of each set do not cross, otherwise the resulting linkage will prevent release from the central carrier despite removal of the inner catheter.

As depicted in FIG. **26**, caudal end **241** of inner and outer catheters **229** and **230** has a short flexible extension (with dimensions and structure similar to carrier stem **220**). Both inner and outer catheters have injection ports **232** and **242**, respectively, at the caudal end of this extension. The injection ports may be locked together with well-known lock **243** to prevent premature removal of the inner catheter.

As depicted in FIG. **23**, cranial end **244** of the carrier shaft (or the caudal end of carrier stem **220**) includes annular groove **245** for attachment of the catheters and sutures.

The diameter of carrier head **219** and shaft **218** are determined by the diameter of introducer sheath **217**, which in turn is dictated by the volume of the prosthesis. The minimum length of the carrier stem is the distance from the proximal end of the aneurysm to the skin of the groin. The maximum length of the carrier shaft is the length of the introducer sheath (which must exceed the length of the carrier stem). Therefore, central carrier **216** is at least twice as long as the iliac artery and aneurysm combined.

The mechanisms of caudal limb control will now be described. All caudal limb control mechanisms extend from caudal ends of limbs **210** and **213** of graft **206** to the level of the skin. Caudal limb control mechanisms take the form of detachable tubular extensions **246** and **247** of the graft as depicted in FIGS. **28** and **29**, or, alternatively, combinations of catheters and/or sutures as depicted in FIGS. **32–35**. Both mechanisms must be amenable to controlled release from the graft by manipulations of the caudal end thereof which extends outside the body.

As depicted in FIG. **28**, tubular extensions **246** and **247** are sutured to the respective caudal ends of limbs **213** and **210** of graft **206** by chain stitches **248** and **249**, which unravel when cut. These chain stitches are anchored by respective locking stitches **250** and **251**. An alternative mechanism depicted in FIG. **29** involves loops of suture **252** and **253** that pass along the wall of respective tubular extensions **246** and **247** to the junction with graft **206**.

Alternatively, as depicted in FIG. **30**, a single loop of suture material **254** is used as the primary means of applying traction to one point on the end of the caudal limb **213**. Attachment to multiple points on the end of caudal limb **210** is depicted in FIG. **31**. When the one side of caudal limb control suture **154** is cut, traction on the other side pulls the end of the suture through the graft and out of the body. Enclosing the suture in catheter **255** reduces the chances of inadvertent tangling. Side ports **256** on catheter **255** in FIG. **32** and multiple side ports **257** and **258** on catheter **255** in FIG. **33** allow traction to be applied to more then one point on the graft without necessarily approximating the wall of limb **210**. Knot **259** ensures that suture **254** comes out with catheter **255** when the ends are freed by dividing both sides of the loop. Catheter/suture combinations can also serve more than one function, because the tension is only transmitted through shortest suture **260** as depicted in FIG. **34**. Traction on catheter **255** does not tighten suture **261** until suture **260** is cut.

However, the two functions of limb control and guided access to the graft lumen can only be performed simultaneously if they are performed by separate catheters. FIG. **35** depicts caudal limb control catheter **255** of contralateral limb **210**. Caudal limb control system **262** includes catheter **255** and suture **263**.

As depicted in FIG. **36**, guided access to the caudal lumen of contralateral limb **210** is provided by a catheter **264** which is moored to the central carrier in the same manner as loops **237** and **238** on the prosthesis. Contralateral lumen access guidance system **265** becomes tense and inflexible when traction is applied to its outer end. When tense, it functions as a guide wire within the lumen of the stent insertion device **140** as depicted in FIG. **39**. Contralateral limb access guidance system **265** is released from central carrier **216** when inner catheter **229** is removed. Mooring loop **266** is attached to the end of the catheter or passes through its lumen to the caudal end (where a knot prevents suture retraction). Sutures that are tied through side holes **267** in the catheter have a tendency to pull out when tension is applied unless the suture also encircles part of the catheter to distribute traction more evenly as depicted in FIG. **37**.

As depicted in FIG. **38**, access to the lumen of the ipsilateral limb **213** is guided by the same wire that is used for angiography and for insertion of the delivery system. If traction is to be maintained during insertion of a stent on the ipsilateral side, a caudal limb control catheter **254** is also required on ipsilateral distal limb **213**.

The orientation of the contralateral limb (and associated catheters) to the carrier must be constant, because any twists are subsequently reproduced in the relative orientation of the two distal limbs. As an additional precaution, the location of contralateral limb **210** is marked on the outside of the delivery system.

Catheters may be made of any plastic that is flexible yet strong enough to hold sutures with extreme thin-walled construction. All sutures should be strong yet fine enough to pass through small catheters. They should also have a low coefficient of friction, to enhance removal at the end of the procedure. Many monofilament and coated multifilament sutures satisfy these criteria. Catheters must be long enough to be accessible at the groin when the contralateral limb has been pulled into position.

Depicted in FIG. **39** is caudal stent insertion device **140** including stent pusher **271** and outer sheath **268**. The basic structure and function of the caudal stent insertion device is similar to prosthesis delivery system **180**.

Caudal stent insertion device introducer sheath **268** is of constant diameter and wall thickness, except at cranial orifice **269** where the external surface of the sheath tapers to meet the surface of pusher head **270** in a smooth transition. The sheath is made of flexible, inert plastic with a low coefficient of friction. The wall of the sheath may incorporate mechanisms to resist kinking (such as an internal wrap of metal wire). At the cranial end of stent pusher **271** is pusher head **270**, which has an external diameter that matches the internal diameter of the introducer sheath. Pusher shaft **272** also matches the diameter of the introducer sheath. Between the two is a narrow pusher stem **273**, which passes through the center of caudal stent **275**.

Depicted in FIG. **40** is contralateral limb straightening device **130** for orienting the position of contralateral limb **210** of graft **206**. Translocation of the contralateral limb of the bifurcated graft can produce twists, straightening device **130** is advanced over the distal limb control system onto the end of the distal limb and rotated to remove twists. The contralateral limb straightening device is a catheter or small gauge dilator with a fish-mouth split at cranial end **274**. The terminal split occupies a plane that also contains the long axis of the device. When traction is applied to suture **254** of the contralateral distal limb control system, the suture is pulled into the catheter approximating the two walls of the graft. The flattened contralateral limb then slides into the slot of the advancing straightening device. Torsion on the device is transmitted to the end of the graft to straighten any twists.

Depicted in FIG. **41** is an alternative limb straightening device **131** designed primarily for use with the system of tubular graft extensions **246** and **247**. The alternative device is a dilator with a soft rounded tip and a bulbous dilation **132** at cranial end **133**. The dilatation is pushed into a narrowing of the tubular extension, which is maintained under tension by traction on the caudal end. The tight fit enables torsional forces to be transmitted to the graft through friction at the surface of the dilatation. In the absence of the tubular graft extensions, the alternative limb straightening device is advanced over contralateral lumen access guidance system **265**. The dilatation then engages the inner aspect of the distal limb orifice **209**. Alternatively, the dilatation may take the form of a balloon, which is inflated inside caudal limb **210**. Whatever form the straightener takes, it must be long enough to reach the end of the caudal limb from the femoral arteriotomy. The diameter is variable, depending on the mechanism of graft attachment. The device must be flexible, yet resist deformation when torsional stresses are applied to the caudal end.

Depicted in FIG. **42** is a sectioned view twist-preventing, double lumen catheter **120**. This soft, flexible catheter has two lumens **121** and **122**. One is occupied by the cross femoral catheter, while the other is occupied by the angiographic catheter (or wire). Cranial end **123** is slightly tapered for ease of insertion. The catheter resists torsion so that the relative orientation of the two lumens is maintained. The twist-preventing, double lumen catheter is inserted to the point where the two catheters diverge, one passing through the aneurysm to the proximal aorta, the other crossing to the opposite iliac artery.

The method for inserting the prosthesis and use of the insertion instruments is hereinafter described. Patients are selected for this procedure on the basis of radiographic imaging (including angiography) and general physical condition.

The patient is placed in the supine position on a radiolucent operating table. Access to the arterial tree may be obtained by surgical isolation of the femoral vessels in the groin. Alternatively, the insertion may be performed through large introducer sheaths placed by percutaneous techniques. In the open technique, silastic bands around the common femoral arteries provide proximal hemostasis, while non-crushing clamps provide distal hemostasis. Most patients will be anticoagulated with heparin prior to the interruption of the circulation to the legs.

Insertion is guided by fluoroscopy. When available, digital subtraction processing enhances fluoroscopic images and is used to record angiograms. Another useful feature of digital subtraction imaging equipment is the "roadmapping" function, which combine real time fluoroscopic images with static angiograms. The composite image facilitates guidance of the apparatus through the vascular tree.

An initial angiogram is performed to provide the reference points that guide insertion. Angiography will frequently have been performed as part of the selection procedure, in which case measurements determining graft size and form will already have been taken. After initial angiography the catheter is removed, leaving the guide wire in place.

A wire, suture, catheter or tape is passed from one femoral artery to the other. In one method, a Dormier basket is passed up the ipsilateral femoral artery and opened over the contralateral iliac artery orifice. A catheter or guide wire is threaded up the opposite femoral artery through the wires of the Dormier basket, which is then closed and withdrawn. The procedure is swift and relatively atraumatic, especially if a very soft, flexible catheter is used. An alternative method involves fluoroscopically guided manipulation of the curved tip of a catheter/guide wire system from one iliac artery into the other.

Care must be taken to avoid winding the angiographic catheter around the cross femoral system. This may be accomplished by inserting the angiographic catheter (or wire) through one lumen of a double lumen, twist-preventing catheter **120**, while the other lumen is occupied by the cross femoral system (or vice versa).

The introducer system is threaded over the same guide wire that occupied the lumen of the angiographic catheter. Fluoroscopic visualization is relatively easy because all components of the apparatus (except the fabric of the graft) are radio-opaque. The position of the prosthesis is controlled during extrusion by manipulation of the central carrier. When the introducer sheath is withdrawn, the stents expand, opening the graft and fixing it in position. Further withdrawal of the introducer sheath **217** exposes the caudal limb control mechanisms and their attachment to central carrier **216**. The caudal limb control mechanisms, such as suture loops **237** and **238** or other catheters, sutures, or tubular graft extensions, are attached to the cross femoral system (catheter, suture, tape or guide wire) using sutures, tape or clips. Traction on the cross femoral system (at the contralateral groin) pulls the contralateral limb **210** into the contralateral iliac artery.

The contralateral limb **210** is sometimes twisted after translocation to the contralateral iliac artery. Twisting is revealed by the fluoroscopic appearance of the radio-opaque lines **211** and **212**. The contralateral limb control mechanism such as suture loops **237** and **238** is used to apply traction to other contralateral limb **210** and pull it onto the advancing contralateral limb straightening device **130** or **131**. Straightening is guided by the fluoroscopic appearance and the character of the femoral arterial pulse and blood flow.

Stents are occasionally required to prevent retrograde leakage of blood around the caudal limbs **210** and **211** back into the aneurysm. The distal stent insertion device may be passed through the lumen of a tubular graft extension **247**. Alternatively, the stent insertion device is passed over a guide wire or over contralateral lumen access guidance system **265**. Whichever method is used, it is usually necessary to maintain traction on the caudal limbs using the caudal limb control mechanism. Insertion of the ipsilateral stent cannot be performed until the delivery system has been removed.

The prosthesis **228** is released from the central carrier **216** by removal of the inner catheter **229**. It is important to replace the inner catheter and advance the guide wire through the central lumen before removing the delivery system, because the wire is needed to guide the stent insertion device into the lumen of the ipsilateral caudal limb **213**. After stent insertion the wire is needed again to guide insertion of a catheter for completion angiography. If angiographic appearances are satisfactory, the catheters are removed, the arteries repaired, and the wounds closed.

What is claimed is:

1. A self-expanding prosthesis delivery system comprising:

a tubular introducer sheath having a sheath bore of a substantially constant diameter extending longitudinally therethrough; and

a central carrier coaxially positionable within said sheath bore of said sheath, said central carrier including a vascular dilator head region having a fixed shape and a portion mating with and approximating said substantially constant diameter of said sheath bore, a shaft region approximating said substantially constant diameter of said sheath bore, and a stem region positioned between said head and shaft regions and being smaller than said substantially constant diameter of said sheath bore for positioning coaxially a self-expanding prosthesis therearound and in said sheath bore.

2. The delivery system of claim **1** wherein said central carrier includes an outer catheter including said vascular dilator head, stem, and shaft regions and an internal lumen extending longitudinally therein and an inner catheter positionable in said internal lumen of said outer catheter.

3. The delivery system of claim **2** wherein said outer catheter includes at least one hole extending transversely through said stem region and communicating with said internal lumen and wherein said system further comprises at least one suture loop positionable in said at least one hole and about said internal catheter for releasably attaching the self-expanding prosthesis to said stem region.

4. The delivery system of claim **3** further comprising a limb control mechanism releasably attached to a limb of the self-expanding prosthesis.

5. The delivery system of claim **4** wherein said limb control mechanism includes a detachable tubular extension.

6. The delivery system of claim **4** wherein said limb control mechanism includes a control suture releasably attached to said limb and a control catheter having a lumen with said control suture positioned therethrough.

7. The delivery system of claim **6** wherein said control catheter includes first and second side ports about a cranial end thereof with said control suture positioned therethrough.

8. The delivery system of claim 4 further comprising a limb straightening device insertable over said limb control mechanism for engaging and straightening said limb of the self-expanding prosthesis.

9. The delivery system of claim 3 further comprising a caudal stent insertion device insertable in a limb bore of said self-expanding prosthesis, said insertion device including an outer sheath, a stent pusher positionable within said outer sheath and having a stem for positioning a caudal stent therearound when in said outer sheath.

10. The delivery system of claim 2 further comprising a twist prevention double lumen catheter for positioning a cross femoral guide and an angiographic guide used in positioning said central carrier.

11. A self-expanding prosthesis delivery system comprising:

an introducer sheath having a uniform sheath bore extending longitudinally therethrough; and

a central carrier coaxially positionable within said uniform sheath bore of said sheath, said central carrier including a vascular dilator head region having a fixed shape and a portion mating with and approximating said uniform sheath bore, a shaft region approximating said uniform sheath bore, and a stem region positioned between said head and shaft regions and being smaller than said uniform sheath bore for positioning coaxially a self-expanding prosthesis therearound and in said sheath bore.

12. The delivery system of claim 11 wherein said central carrier includes an outer catheter including said vascular dilator head, stem, and shaft regions and an internal lumen extending longitudinally therein and an inner catheter positionable in said internal lumen of said outer catheter.

13. The delivery system of claim 12 wherein said outer catheter includes at least one hole extending transversely through said stem region and communicating with said internal lumen and wherein said system further comprises at least one suture loop positionable in said at least one hole and about said internal catheter for releasably positioning the self-expanding prosthesis with respect to said stem region.

14. The delivery system of claim 13 further comprising a caudal stent insertion device insertable in a limb bore of the self-expanding prosthesis, said insertion device including an outer sheath, a stent pusher positionable within said outer sheath and having a stem for positioning a caudal stent therearound when in said outer sheath.

15. The delivery system of claim 13 further comprising a limb control mechanism releasably attached to a limb of the self-expanding prosthesis.

16. The delivery system of claim 15 wherein said limb control mechanism includes a detachable tubular extension.

17. The delivery system of claim 15 wherein said limb control mechanism includes a control suture releasably attached to the limb and a control catheter having a lumen with said control suture positioned therethrough.

18. The delivery system of claim 17 wherein said control catheter includes first and second side ports about a cranial end thereof with said control suture positioned therethrough.

19. The delivery system of claim 15 further comprising a limb straightening device insertable over said limb control mechanism for engaging and straightening the limb of the self-expanding prosthesis.

20. The delivery system of claim 12 further comprising a twist prevention double lumen catheter for positioning a cross femoral guide and an angiographic guide used in positioning said central carrier.

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(54) **EXPANDABLE TRANSLUMINAL GRAFT PROSTHESIS FOR REPAIR OF ANEURYSM**

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(58) **Field of Classification Search** ..... None
See application file for complete search history.

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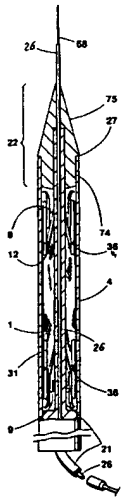
(57) **ABSTRACT**

A transluminal grafting system for grafting a prosthesis to the wall of a lumen includes a tubular graft provided with spring assemblies and anchoring barbs. The prosthesis is mounted on an apertured tubular carrier and a central control means is inserted into the bore of the apertured carrier. Mooring loops are attached to the prosthesis, pass through the apertures of the tubular carrier, and engage the central control means. An introducer sheath covers the system for smooth insertion into a lumen. When the graft has been positioned, the central control means maintains the axial position of the prosthesis. When the introducer sheath is pulled, the prosthesis is exposed and the spring assemblies return to an expanded state and anchor the graft against the internal wall of the lumen.



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EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

Claim **11** is cancelled.

Claim **1** is determined to be patentable as amended.

Claims **21-33** are added and determined to be patentable.

Claims **2-10** and **12-20** were not reexamined.

1. A self-expanding prosthesis delivery system comprising:

a tubular introducer sheath having a sheath bore of a substantially constant diameter extending longitudinally therethrough; **[**and**]**

a central carrier coaxially positionable within said sheath bore of said sheath, said central carrier including a vascular dilator head region having a fixed shape and a portion mating with and approximating said substantially constant diameter of said sheath bore, a shaft region approximating said substantially constant diameter of said sheath bore, and a stem region positioned between said head and shaft regions and being smaller than said substantially constant diameter of said sheath bore for positioning coaxially a self-expanding prosthesis therearound and in said sheath bore;

said self-expanding prosthesis positioned in said sheath bore and around said stem region, said self-expanding prosthesis comprising a graft configured to span an aortic aneurysm and form a conduit from an aorta to an iliac artery and a spring assembly attached to an inside of said graft;

said graft further comprising a bifurcated graft comprising a main body with a cranial orifice and a main bore, an ipsilateral graft limb extending from said main body and comprising a first bore communicating with said main bore and a first caudal orifice, and a contralateral graft limb extending from said main body and comprising a second bore communicating with said main bore and a second caudal orifice, said main bore and said first bore being positioned around said stem region;

wherein said spring assembly is formed from a continuous wire in the shape of a zig-zag with multiple elbows, and further comprising at least a first of said spring assembly and a second of said spring assembly, said first assembly comprising an aperture and said second spring assembly comprising a longitudinal member slidably disposed through said aperture, said longitudinal member further comprising a portion with a dimension that is larger than said aperture to prevent disengagement of said first and second spring assemblies;

wherein at least one of said spring assembly is attached with sutures to said inside of said graft only at one or more ends of said graft;

a seal disposed at a proximal end of said introducer sheath and comprising an aperture configured to receive said central carrier; and

wherein said delivery system is characterized by the absence of a guiding catheter.

21. A self-expanding prosthesis delivery system comprising:

an introducer sheath having a uniform sheath bore extending longitudinally therethrough;

a central carrier coaxially positionable within said uniform sheath bore of said sheath, said central carrier including a vascular dilator head region having a fixed shape and a portion mating with and approximating said uniform sheath bore, a shaft region approximating said uniform sheath bore, and a stem region positioned between said head and shaft regions and being smaller than said uniform sheath bore for positioning coaxially a self-expanding prosthesis therearound and in said sheath bore; and

a seal disposed at a proximal end of said introducer sheath and comprising an aperture configured to receive said central carrier.

22. A self-expanding prosthesis delivery system comprising:

an introducer sheath having a uniform sheath bore extending longitudinally therethrough; and

a central carrier coaxially positionable within said uniform sheath bore of said sheath, said central carrier including a vascular dilator head region having a fixed shape and a portion mating with and approximating said uniform sheath bore, a shaft region approximating said uniform sheath bore, and a stem region positioned between said head and shaft regions and being smaller than said uniform bore for positioning coaxially a self-expanding prosthesis therearound and in said sheath bore;

wherein said central carrier further comprises a lip overlapping an end of said introducer sheath so that no edges of said end are presented to an arterial lumen.

23. A self-expanding prosthesis delivery system comprising:

an introducer sheath having a uniform sheath bore extending longitudinally therethrough; and

a central carrier coaxially positionable within said uniform sheath bore of said sheath, said central carrier including a vascular dilator head region having a fixed shape and a portion mating with and approximating said uniform sheath bore, a shaft region approximating said uniform sheath bore, and a stem region positioned between said head and shaft regions and being smaller than said uniform sheath bore for positioning coaxially a self-expanding prosthesis therearound and in said sheath bore;

wherein said delivery system is characterized by the absence of a guiding catheter.

24. A self-expanding prosthesis delivery system comprising:

an introducer sheath having a uniform sheath bore extending longitudinally therethrough; and

a central carrier coaxially positionable within said uniform sheath bore of said sheath, said central carrier including a vascular dilator head region having a fixed shape and a portion mating with and approximating said uniform sheath bore, a shaft region approximating said uniform sheath bore, and a stem region positioned

between said head and shaft regions and being smaller than said uniform sheath bore for positioning coaxially a self-expanding prosthesis therearound and in said sheath bore; and

said self-expanding prosthesis positioned in said sheath bore and around said stem region, said self-expanding prosthesis comprising a graft configured to span an aortic aneurysm and form a conduit from an aorta to an iliac artery and a spring assembly attached to an inside of said graft.

25. The delivery system of claim 24 wherein said spring assembly is attached to said graft such that a portion of said spring assembly is covered by said graft and another portion of said spring assembly extends beyond a distal end of said graft.

26. The delivery system of claim 24 wherein at least one of said spring assembly is attached with sutures to said inside of said graft only at one or more ends of said graft.

27. The delivery system of claim 24 further comprising at least a first of said spring assembly and a second of said spring assembly, said first spring assembly comprising an aperture and said second spring assembly comprising a longitudinal member slidably disposed through said aperture.

28. The delivery system of claim 27 wherein said longitudinal member comprises a portion with a dimension that is larger than said aperture to prevent disengagement of said first and second spring assemblies.

29. The delivery system of claim 24 wherein said spring assembly is formed from a continuous wire in the shape of a zig-zag with multiple elbows, and further comprising at least a first of said spring assembly and a second of said spring assembly, said first spring assembly comprising an aperture and said second spring assembly comprising a longitudinal member slidably disposed through said aperture.

30. A self-expanding prosthesis delivery system comprising:

an introducer sheath having a uniform sheath bore extending longitudinally therethrough; and

a central carrier coaxially positionable within said uniform sheath bore of said sheath, said central carrier including a vascular dilator head region having a fixed shape and a portion mating with and approximating said uniform sheath bore, a shaft region approximating said uniform sheath bore, and a stem region positioned between said head and shaft regions and being smaller than said uniform sheath bore for positioning coaxially a self-expanding prosthesis therearound and in said sheath bore; and

said self-expanding prosthesis comprising a bifurcated graft comprising a main body with a cranial orifice and a main bore, an ipsilateral graft limb extending from said main body and comprising a first bore communicating with said main bore and a first caudal orifice, and a contralateral graft limb extending from said main body and comprising a second bore communicating with said main bore and a second caudal orifice, said main bore and said first bore being positioned around said stem region.

31. The delivery system of claim 30 further comprising a twist prevention double lumen catheter for positioning a cross femoral guide and an angiographic guide used in positioning said central carrier.

32. The delivery system of claim 30 further comprising a catheter attached to a caudal end of said contralateral graft limb.

33. The delivery system of claim 30 further comprising a guidewire extending through said second bore of said contralateral graft limb.

* * * * *

Exhibit B

United States Patent [19]

Giantureo et al.

[11] **Patent Number: 5,035,706**

[45] **Date of Patent: Jul. 30, 1991**

[54] **PERCUTANEOUS STENT AND METHOD FOR RETRIEVAL THEREOF**

[75] Inventors: **Cesare Giantureo**, Champaign, Ill.; **Thomas A. Osborne**, Bloomington, Ind.

[73] Assignee: **Cook Incorporated**, Bloomington, Ind.

[21] Appl. No.: **422,606**

[22] Filed: **Oct. 17, 1989**

[51] **Int. Cl.**[5] **A61M 29/00**

[52] **U.S. Cl.** **606/198**

[58] **Field of Search** 606/108, 153, 154, 155, 606/156, 198, 200, 191; 604/105, 106

[56] **References Cited**

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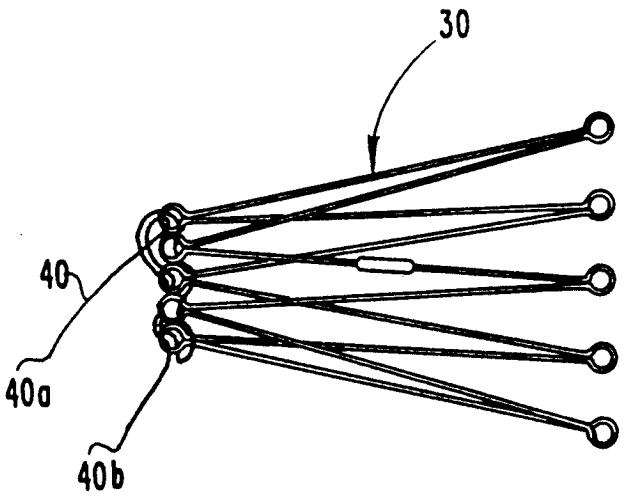
Primary Examiner—Michael H. Thaler
Attorney, Agent, or Firm—Woodard, Emhardt, Naughton, Moriarty & McNett

[57] **ABSTRACT**

A self-expanding stent formed of stainless steel wire arranged in a closed zig-zag configuration includes an endless series of straight sections joined at their ends by bends. The stent is compressible into a reduced diameter size for insertion into and removal from a body passageway. The bends of at least one end of the stent are formed into eyes for connection with the eyes at one end of a similarly constructed stent to permit single-step introduction of several lengths of stent into the passageway. A stent can include a monofilament thread passing through successive eyes at one end of the stent, the thread passing through each eye at least once and through some of the eyes a second time. The trailing ends of the thread extend from the stent and outside the body passageway. The stent can be retrieved from the body passageway by threading a tube of the free ends of the thread until the tube is adjacent the stent. The diameter at one end of the stent is reduced by pulling the free ends of the thread through the tube. A sheath concentrically disposed over the tube is introduced into the body passageway and over the remaining length of the stent to further compress the stent for removal from the passageway.

12 Claims, 4 Drawing Sheets



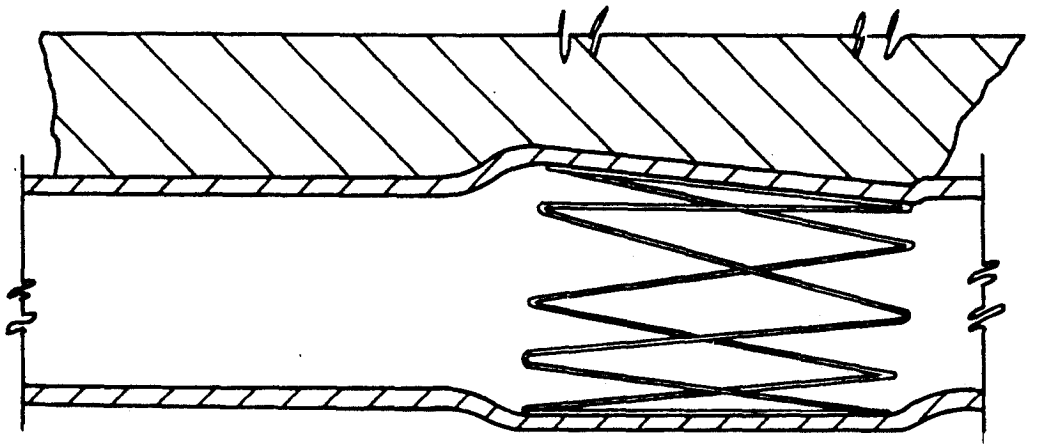


Fig.1
PRIOR ART

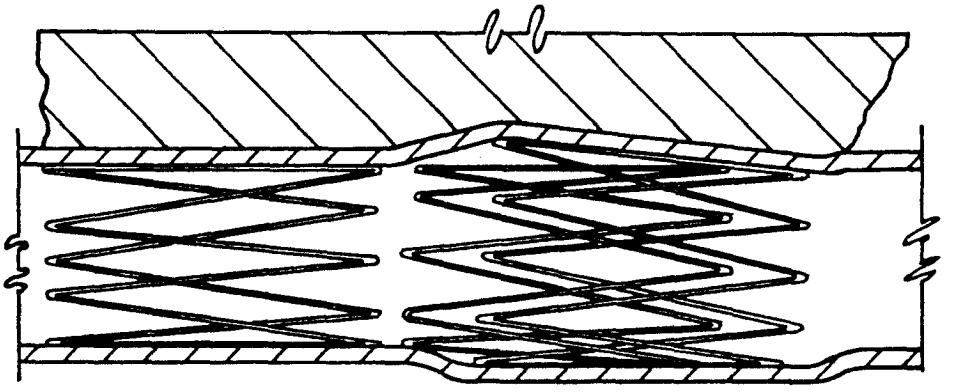


Fig.2
PRIOR ART

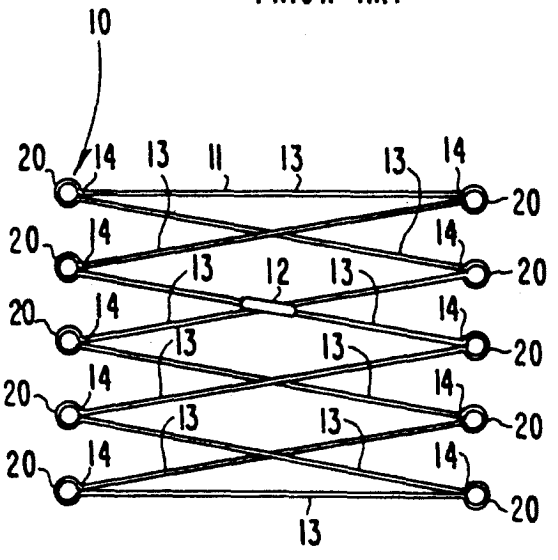


Fig.3

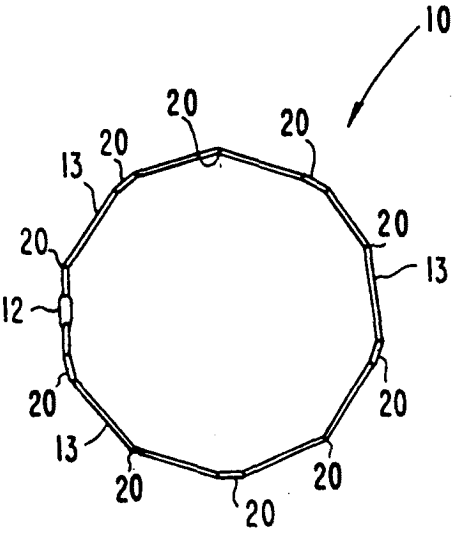


Fig.4

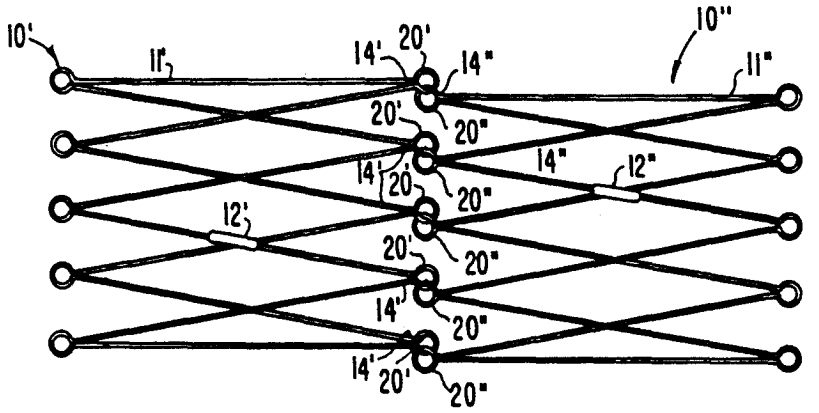


Fig.5

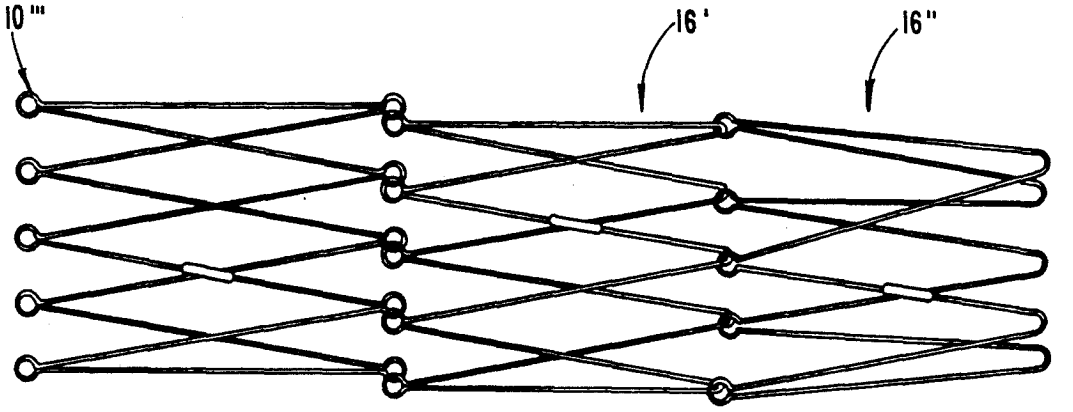


Fig.6

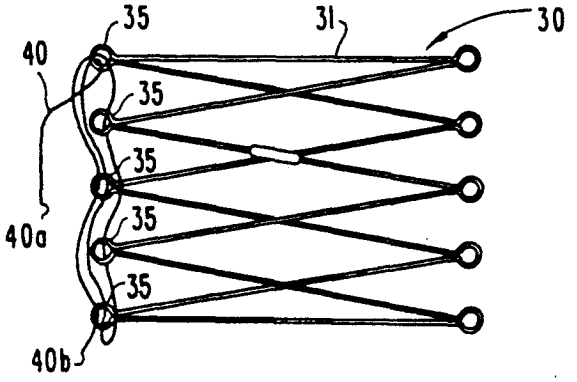


Fig.7A

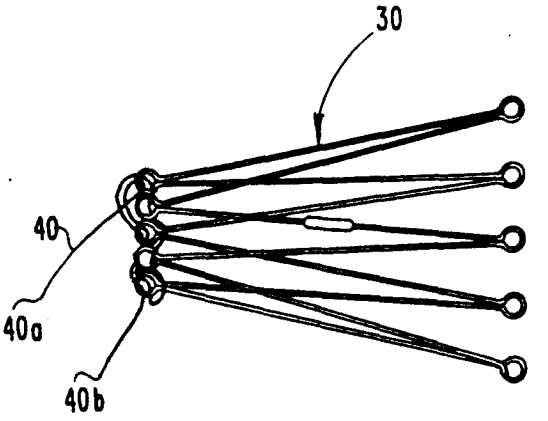


Fig.7B

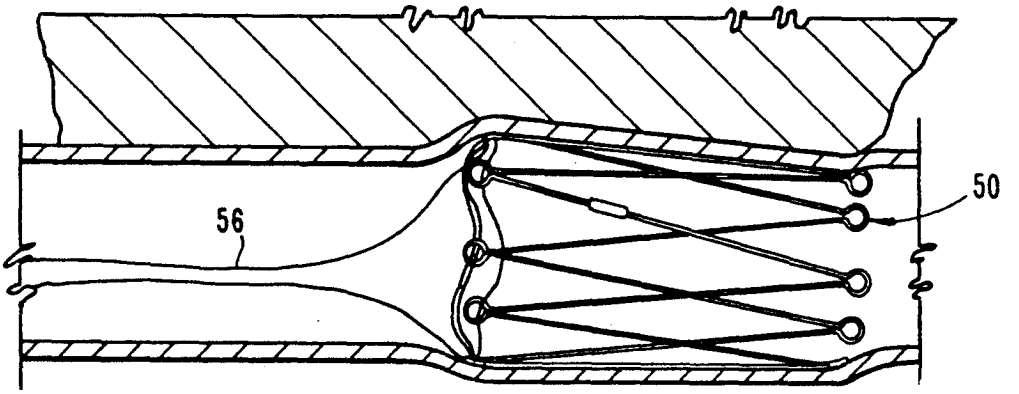


Fig.9

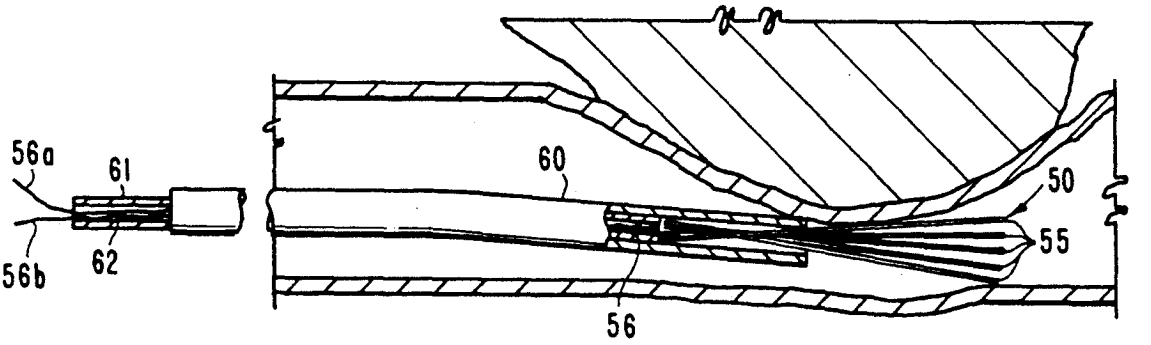


Fig.8

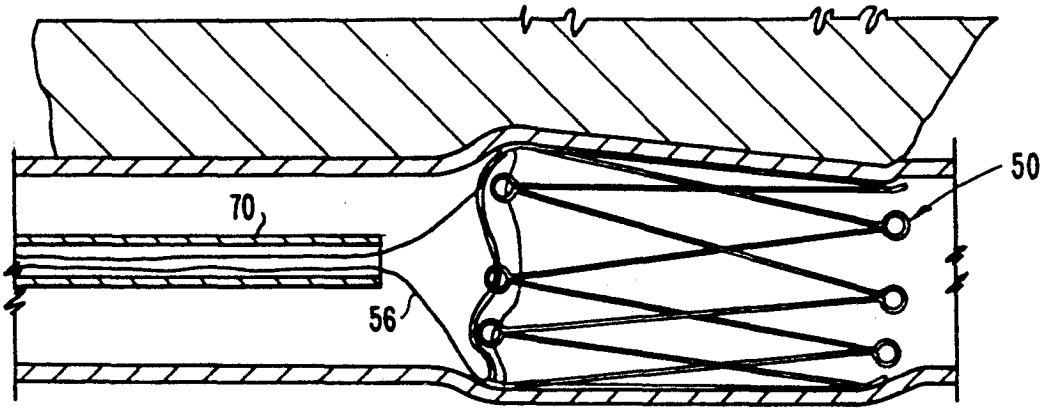


Fig.10A

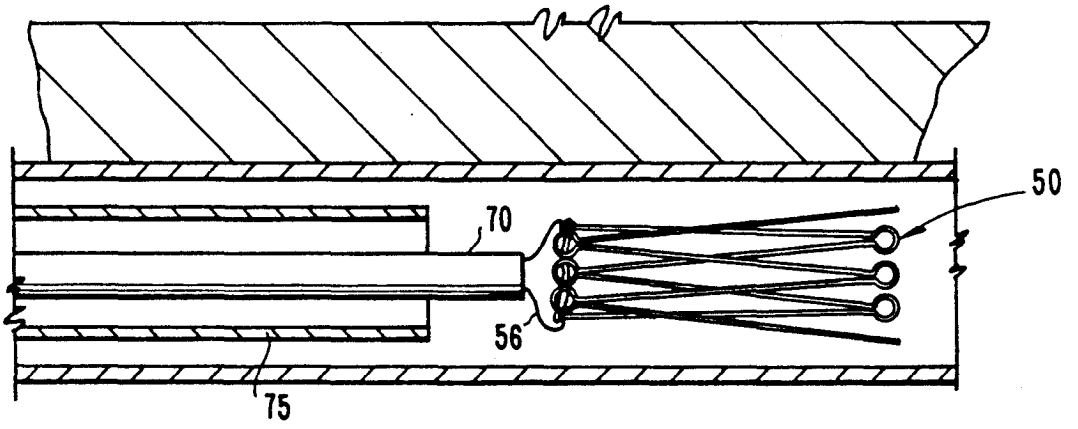


Fig.10B

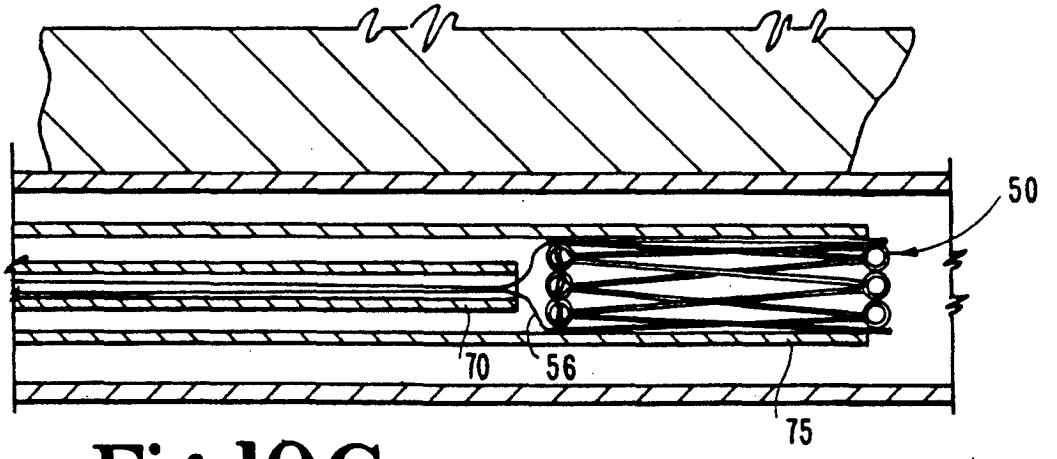


Fig.10C

PERCUTANEOUS STENT AND METHOD FOR RETRIEVAL THEREOF

BACKGROUND OF THE INVENTION

This invention relates to stents and a method for retrieving stents after insertion into the body of a patient. In particular, the invention relates to modifications to the Gianturco Expandable Wire Stent.

It is desirable in various situations to provide means for expanding a constricted vessel portion or for maintaining an open passageway through a vessel portion. Such situations arise, for example, in conjunction with arteriosclerosis that restricts or stops blood flow through a vessel, or in conjunction with diseases of the prostrate gland which resrict or stop flow through the urethra.

A percutaneous stent developed by Dr. Cesare Gianturco is formed of a stainless steel wire arranged in a closed, zig-zag pattern, as more fully described in U.S. Pat. No. 4,580,568. The Gianturco stent, or the Z-stent as it is also known, is compressed into a reduced size shape with an outer diameter which is many times smaller its outer diameter in an expanded shape. The stent is positioned in a passageway by means of a sheath while the stent is retained in the compressed reduced size shape. A pusher or flat-ended catheter is used through the sheath to hold the stent in place in the passageway while the sheath is withdrawn, thereby allowing the stent to expand in the passageway into its expanded shape to hold the passageway open and enlarged. Thus, the Z-stent provides a self-expanding means for maintaining an open passageway. FIG. 1 illustrates the use of the well-known Z-stent wire within a body passageway.

FIG. 2 illustrates the use of several Z-stents along a limited length of a body passageway. In illustrated arrangement, two stents are situated in an overlapping arrangement, while a third stent is disposed slightly downstream from the other two stents. As discussed more fully in the above-referenced Gianturco '568 patent, each of the three stents must be separately inserted using the sheath and pusher described above.

Since the initial development of the expandable wire Z-stent, it has been discovered that over time a Z-stent may continue to expand to its maximum diameter even though it was originally deployed in a passageway that had a diameter somewhat smaller than the maximum outer diameter of the expanded stent. Thus, the end result has been in some cases that the stent becomes embedded deeply into the walls of the passageway. In an effort to address this particular problem, others in the art have modified the expandable Z-stent to form eyes at the bends or joints of the zig-zag configuration. A monofilament line is then threaded through each of the eyes at one end of the stent to form, in essence, a continuous flexible ring which restricts the expansion of the wire stent. The monofilament line is sufficiently elastic in the tensile direction to control the expansion of the stent to an optimal desired diameter.

Further description of this modified expandable wire Z-stent is found in the following references:

Modified Gianturco Expandable Wire Stents in Experimental and Clinical Use, J. Rosch, CIRSE, Porto Cervo, Sardinia, May 25–29, 1987, Vol 31-No. 2, 1988

Modifications of Gianturco Expandable Wire Stents, Barry T. Uchida, AJR 150:1185–1187, May 1988, American Roentgen Ray Society

Experimental Intrahepatic Portacaval Anastomosis: Use of Expandable Gianturco Stents, Josef Rosch, M.D., RSNA, 1987, Volume 162 No. 2

Superior Vena Cava Syndrome Associated with Massive Thrombosis: Treatment with Expandable Wire Stents, RSNA, June 1988

Gianturco Expandable Wire Stents in the Treatment of Superior Vena Cava Syndrome Recurring After Maximum-Tolerance Radiation, Reprinted from CANCER, Vol. 60, No. 6, Sept. 15, 1987.

There remains, however, a need for a percutaneous stent that is self-expanding, yet can be retrieved after a period of time of insertion. There is also need for a percutaneous stent that includes several stent sections for insertion along a greater length of a body passageway than has been permitted by expandable stents of the prior art. There is also a need for a stent capable of combination with multiple stent sections that does not require multiple catheterizations for insertion operations.

SUMMARY OF THE INVENTION

One embodiment of the self-expanding stent of the present invention includes a wire formed into a closed zig-zag configuration defining an endless series of straight sections joined by bends. At each of the bends is formed an eye which can be used for connection of another similarly constructed self-expanding stent, or for connection of a skirt stent of like construction. A number of self-expanding stents can be combined by joining the stents at the eyes. Each of the stents is resiliently compressible into a first smaller shape for insertion into a body passageway, such as through an introducer sheath. Once within the body passageway, the stents are resiliently expandable into a larger second shape wherein the straight sections press against the walls of the passageway to maintain it open.

Another embodiment of the invention involves a self-expanding stent of closed zig-zag configuration having eyes at bends joining the straight sections of the stent. A monofilament thread is passed through each of the eyes at one end of the stent, once through each of the eyes in a 360° loop and then again 180° through some of the eyes. The trailing free ends of the monofilament leave the stent at opposite sides of the stent diameter and extend through an introducer sheath outside the body passageway. The monofilament can be tied externally to limit the expansion of the self-expanding stent within the body passageway.

The free ends of the monofilament can also be used to reduce the diameter of the stent to permit retrieval of the stent from the body passageway. Thus, in a method of the invention, a tube is threaded over the free ends of the monofilament and advanced along the passageway until the tube is adjacent the expanded stent. The free ends are then pulled thereby contracting the outer diameter of the stent until the diameter is approximately equal to the diameter of the tube. A sheath can then be introduced over the tube and over the reduced diameter portion of the stent to further collapse the remaining length of the stent. The entire assembly, including the tube, sheath, stent and monofilament can then be removed from the body passageway.

One object of the invention is to provide a self-expanding stent that permits the combination of several

interlocked stents for insertion into a body passageway. Another object of the invention is to provide a method for removal of a self-expanding stent situated within a body passageway. Other objects and benefits of the present invention can be discerned from the following written description of the invention along with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is side cross-sectional view of a body passageway with a self-expanding wire stent of the prior art situated therein.

FIG. **2** is a view similar to FIG. **1** showing the use of several stents of the prior art within the body passageway.

FIG. **3** is a side elevational view of a preferred embodiment of the present invention.

FIG. **4** is an end elevational view of the structure of FIG. **3**.

FIG. **5** is a side elevational view of another embodiment of the present invention.

FIG. **6** is a side elevational view of another embodiment of the present invention.

FIG. **7A** is a side elevational view of still another embodiment of the present invention shown in its expanded state.

FIG. **7B** is a side elevational view of the structure of FIG. **7A** shown with one end in its contracted state.

FIG. **8** is a sectional view of a body passageway showing a method of insertion of the self-expanding stent of the present invention.

FIG. **9** is a sectional view of the body passageway similar to FIG. **8** following insertion of the self-expanding stent.

FIG. **10A** is a sectional view of the body passageway shown in FIG. **9** showing one step of a method of retrieval of the self-expanding stent of one embodiment of the present invention.

FIG. **10B** is a view similar to FIG. **10A** showing another step of the method of retrieval.

FIG. **10C** is a view similar to FIG. **10B** showing another step of the method of retrieval of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring now more particularly to the drawings, there is illustrated in FIGS. **3–4** a side elevation of a preferred embodiment of the percutaneous stent **10** which is formed from a length **11** of stainless steel wire formed in a closed zig-zag configuration. The ends of the wire are closed by a sleeve **12** which is welded or tightly squeezed against the ends of the wire to produce a continuous or endless configuration. The length **11** of wire is arranged in a number of side-by-side straight sections **13**. Adjacents straight sections **13** of the stents are adjoined by cusps **14**.

Up to this point, the stent **10** of the present invention is, in most respects, similar to the Z-stent described in U.S. Pat. No. 4,580,568, which description is incorporated herein by reference. In particular, the specific embodiment of the invention includes the wire **11** which is of stainless steel having a 0.018 inch outer diameter. The cusps **14**, that is the joint between adjacents straight sections **13**, generally circumscribes a radius of no more than 0.2 cm or about 0.08 inch. As thus configured, the stent **10** is capable of being compressed into a relatively much smaller outer diameter than that shown in FIGS. **3–4**, in order to permit insertion of the stent into the body passageway by use of a catheter or sheath.

In one novel aspect of the present invention, the cusps **14** of the stent are formed into a number of eyes **20**. In the preferred embodiment, the eyes are formed in the continuous wire **11** and the intersection between adjacent straight sections **13** at the cusps **14** are soldered or welded together to provide a closed loop for the eyes **20**. In one specific embodiment of the invention, the eyes have a diameter of approximately three times the wire diameter, or about 0.054 inch.

In another embodiment of the invention, multiple stents are combined as shown in FIGS. **5** and **6**. In the embodiment of FIG. **5**, two self-expanding stents **10'** and **10''** are connected or attached at the eyes **20'** and **20''** at the ends of each of the stents. Each of the stents **10'** and **10''** are generally identical to the stent **10** just described. In constructing the union between the two stents **10'** and **10''**, the first stent **10'** is formed from a single length of stainless steel wire **11'**. The length of wire **11'** is formed into the zig-zag and eye configuration although the cusps **14'** are not immediately soldered. The free ends of the length of wire **11'** are joined by way of the sleeve **12'**. Once the first stent **10'** has been formed, the second stent **10''** is formed from a second length **11''** of stainless steel wire. The second length **11''** is formed into the zig-zag and eye configuration so that the eyes **20''** formed at one end of the stent are interlocked with the eyes **20'** of the first stent **10'**. Once the second stent **10''** is complete, a sleeve **12''** is used to connect the ends of the length of wire **11'** and the cusps **14'** and **14''** can then be joined or soldered.

A similar method of construction can be used to interconnect a stent **10'''**, which is identical to the stent **10** described above, with a single skirt stent **16'**, as shown in FIG. **6**. In this particular embodiment, the single skirt stent **16'** does not have a number of eyes defined at the free end of the skirt. The free end of the skirt **16'** may be formed into the configuration of hooks to prevent migration of the stent and skirt combination once the combination is placed within the body passageway. It is understood that in the embodiments of FIGS. **5** and **6**, the eyes at one end of one stent or skirt may be connected to a stent having only bends or cusps at its connecting end, in a manner similar to the connection between skirt **16'** and a similar skirt **16''** shown in FIG. **6**.

In another embodiment of the present invention, a stent **30** is formed from a length of wire **31** into a zig-zag configuration identical to the stent **10** shown in FIG. **3**. Alternatively, the stent **30** can be connected to a second stent, as shown in FIG. **5**, or to a skirt, as shown in FIG. **6**. A number of eyes **35** are formed at least at one end of the stent **30**. A thread **40**, preferably a monofilament of bio-compatible material, is passed through successive eyes around the circumference of the expanded stent **30**. The thread **40** is passed through the eyes **35** by first

passing one end **40***a* through each successive eye **35** while retaining the other end **40***b* outside and apart from the stent **30**. The first end **40***a* of the thread **40** is threaded once through each of the eyes **35** in a 360° loop and then 180° further through successive eyes, or about 540° around the circumference of the stent, so that some of the eyes **35** will have two passes of the thread **40** therethrough. Thus, as shown in FIG. 7A, the two free ends **40***a* and **40***b* of the thread **40** are situated at 180° opposite eyes **35** of the stent **30**. The thread **40** can then be used to collapse one end of the self-expanding wire stent by pulling both free ends **40***a* and **40***b* of the thread **40**. When the free ends **40***a* and **40***b* are pulled simultaneously, the diameter of the thread **40**, and therefore the diameter of one end of the stent **30**, is decreased. Alternatively, the thread **40** can be used to limit the expanded diameter of the stent by tying the free ends **40***a* and **40***b* directly adjacent the stent.

In using the percutaneous stent of the present invention, an insertion technique similar to that described in the Gianturco '568 patent is employed, as shown in FIG. **8**. A self-expanding stent **50** includes a number of eyes **55** at each end of the stent **50** and is identical in all respects to the stent **30** shown in FIG. 7A. The monofilament thread **56** passes through the eyes **55** at one end of the stent **50**. In the method of insertion, the stent is compressed to its reduced diameter and disposed within a sheath **60**, as shown in FIG. **8**. The free ends **56***a* and **56***b* of the filament **56** extend outside the sheath **60** and exterior to the patient's body for access after the stent has been inserted. For example, when the stent is used as a prostatic stent, the filament **56** has a length of 30 to 40 cm measured from the stent **50** to each of the free ends **56***a* and **56***b*, so that the free ends may extend down from the prostate gland to the end of the urethra. When the stent **50** is used as a vascular stent, the length of the filament **56** may be considerably shorter, provided the ends **56***a* and **56***b* are situated outside the puncture site and are sufficiently long to be anchored onto the skin nearby.

In the preferred embodiment, the free ends **56***a* and **56***b* of the filament **56** are tied together so that they can be easily controlled and maintained. When the stent **50** is compressed within the sheath **60**, a pusher **61** is used to hold the stent **50** in position when the body passageway while the sheath **60** is withdrawn. The pusher **61** may have a channel **62** within which the monofilament **56** can be disposed to prevent any pinching or tugging of the filament while the sheath **60** is being removed. Once the sheath is removed, the pusher **61** can also be removed so that the stent **50** remains in position within the body passageway as shown in FIG. **9**. The monofilament **56** trails the stent and passes outside the body as described above.

In certain medical operations, the stent **50** need only be positioned temporarily within the body passageway. Thus, in another method of the present invention, illustrated with reference to FIGS. **10A–10C**, the stent **50** is retrieved from the body passageway and removed. In the method of this embodiment, a tube **70** is threaded over the free ends of the monofilament **56** and inserted into the body passageway along the monofilament **56** until it is adjacent the implanted stent **50**, as shown in FIG. **10A**. Once the tube **70** is positioned directly adjacent the stent **50**, the free ends of the monofilament **56** can be pulled through the tube **70**, thereby compressing or contracting one end of the stent **50** to a reduced diameter, as shown in FIG. **10B**. With the end of the stent **50** thus compressed, a sheath **75** can be introduced into the body passageway over the tube **70**, as shown in FIG. **10C**. The sheath **75** has an inner diameter larger than the reduced diameter of the end of the stent **50**. The sheath **75** is continually conveyed into the body passageway over the tube **70** until it contacts and compresses the remaining length of the self-expanding stent **50**. Once the sheath **75** completely covers or shrouds the stent **50**, that is when the stent **50** is disposed entirely within the sheath **75**, the entire assembly can be removed from the body passageway. In the preferred embodiment of the present method, the tube **70** and sheath **75** are composed of medical grade plastic, such as an 8-polyethylene tubing.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A stent assembly comprising:

a first wire formed into a closed zig-zag configuration including;

an endless series of straight sections having opposite ends, said straight sections being joined by bends at said opposite ends to form a stent;

a set of eyes formed at several of said bends at one of said opposite ends; and

a thread passing through successive ones of said set of eyes, said thread including a pair of free ends trailing from said stent;

wherein said stent is resiliently contractable into a smaller first shape for conveyance through a body passageway;

wherein said one end of said stent is contractable by drawing said pair of free ends of said thread;

wherein said stent is resiliently expandable into a second shape in which the straight sections press against the walls of the body passageway; and

wherein said free ends are sufficiently long to extend outside the body passageway when said stent is situated within the passageway.

2. The stent assembly of claim **1**, wherein:

said second shape of said stent includes a circumference at said one of said opposite ends, said set of eyes being situated at said circumference; and

said thread passes through successive eyes at least 360° around said circumference.

3. The stent assembly of claim **2**, wherein said thread passes through successive eyes approximately 540° around said circumference.

4. The stent assembly of claim **1**, further comprising:

a second wire formed into a closed zig-zag configuration including;

a second endless series of straight sections having opposite ends, said straight sections being joined by bends at said opposite ends to form a second stent;

a second set of eyes formed at several of said bends at one of said opposite ends;

wherein said second stent is resiliently contractable into a smaller first shape for conveyance through a body passageway;

wherein said second stent is resiliently expandable into a second shape in which the straight sections press against the walls of the body passageway; and

wherein said second set of eyes of said second wire are engaged about said first wire at one of said opposite ends.

5. The stent assembly of claim **4**, wherein:

said first wire includes a third set of eyes formed at several bends at the other of said opposite ends of said first wire; and

said second set of eyes of said second wire are interengaged with said third set of eyes.

6. A method for combining a first and second self-expanding stent to form a stent assembly for insertion into a body passageway comprising the steps of:

forming a first stent from a continuous first length of wire formed into a closed zig-zag configuration having an endless series of straight sections joined at their ends by a plurality of bends;

forming a second stent from a continuous second length of wire formed into a closed zig-zag configuration having an endless series of straight sections joined at their ends by a plurality of bends, the bends at one end defining eyes open at the straight sections of the second stent;

engaging the eyes at the one end of the second stent about bends at one end of the first stent; and

closing the eyes at the one end of the second stent.

7. The method of claim **6** wherein:

the step of forming the first stent includes forming eyes at the one end of the first stent, the eyes open at the straight sections of the first stent; and

the step of engaging the eyes at one end of the second stent includes interlocking the eyes of the second stent with the eyes of the first stent and closing the eyes at the one end of the first stent.

8. A method for retrieving a stent disposed within a body passageway, the stent including a resilient wire formed in a closed zig-zag configuration having a set of eyes formed at one end of the stent, with a thread passing through successive eyes of the stent and having two free ends trailing from the stent outside the body passageway, the stent having a first compressed shape and a second expanded shape in which the resilient wire contacts the wall of the body passageway, comprising the steps of:

pulling the free ends of the thread to reduce the diameter of the one end of the stent while maintaining the position of the stent within the body passageway;

reducing the diameter of the remainder of the stent sufficient to permit travel of the stent through the body passageway;

retracting the compressed stent through the passageway.

9. The method for retrieving a stent of claim **8**, wherein said step of pulling the free ends further includes the steps of:

threading a tube over the trailing free ends of the thread, the tube having an inner diameter smaller than the diameter of the first compressed shape of the stent;

introducing the tube into the body passageway and conveying the tube to a position adjacent the stent;

pulling the free ends of the thread through the tube to reduce the diameter of the one end of the stent.

10. The method for retrieving a stent of claim **9**, wherein said step of reducing the diameter of the remainder of the stent further includes the steps of:

introducing a sheath concentrically disposed over the tube into the body passageway;

conveying the sheath over the tube through the body passageway and over the reduced diameter end of the stent;

further conveying the sheath over the remainder of the stent to compress the remainder of the sheath and withdraw the stent from contact with the wall of the body passageway.

11. The method for retrieving a stent of claim **8**, wherein said step of reducing the diameter of the remainder of the stent further includes the steps of:

threading a sheath over the trailing free ends of the thread, the sheath having an inner diameter larger than the diameter of the first compressed shape of the stent but smaller than the diameter of the second expanded shape of the stent;

introducing the sheath into the body passageway and conveying the sheath through the body passageway and over the reduced diameter end of the stent;

further conveying the sheath over the remainder of the stent to compress the remainder of the sheath and withdraw the stent from contact with the wall of the body passageway.

12. A stent assembly comprising:

a first wire formed into a closed zig-zag configuration including;

an endless series of straight sections having opposite ends, said straight sections being joined by bends at said opposite ends to form a first stent; and

a second wire formed into a closed zig-zag configuration including;

a second endless series of straight sections having opposite ends, said straight sections being joined by bends at said opposite ends to form a second stent;

a set of eyes formed at several of said bends at one of said opposite ends;

wherein said first and second stents are resiliently contractable into a smaller first shape for conveyance through a body passageway;

wherein said first and second stents are resiliently expandable into a second shape in which the straight sections press against the walls of the body passageway; and

wherein said set of eyes of said second stent are engaged about said first wire at one of said opposite ends of said first wire.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,035,706

DATED : July 30, 1991

INVENTOR(S) : Cesare Gianturco et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page, under item [19] and in item [75]:
The inventor's name should be changed from "Giantureo" to --Gianturco--.

Signed and Sealed this

Third Day of November, 1992

Attest:

Attesting Officer

DOUGLAS B. COMER

Acting Commissioner of Patents and Trademarks

US005035706C1

(12) EX PARTE REEXAMINATION CERTIFICATE (7458th)

United States Patent
Gianturco et al.

(10) **Number: US 5,035,706 C1**
(45) **Certificate Issued: Apr. 20, 2010**

(54) **PERCUTANEOUS STENT AND METHOD FOR RETRIEVAL THEREOF**

(75) Inventors: **Cesare Gianturco**, Champaign, IL (US); **Thomas A. Osborne**, Bloomington, IN (US)

(73) Assignee: **Cook Incorporated**, Bloomington, IN (US)

Reexamination Request:
No. 90/010,748, Nov. 23, 2009

Reexamination Certificate for:

Patent No.:	**5,035,706**
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Appl. No.:	**07/422,606**
Filed:	**Oct. 17, 1989**

Certificate of Correction issued Nov. 3, 1992.

(51) **Int. Cl.**
A61M 29/00 (2006.01)

(52) **U.S. Cl.** **606/198**
(58) **Field of Classification Search** ..... None
See application file for complete search history.

(56) **References Cited**

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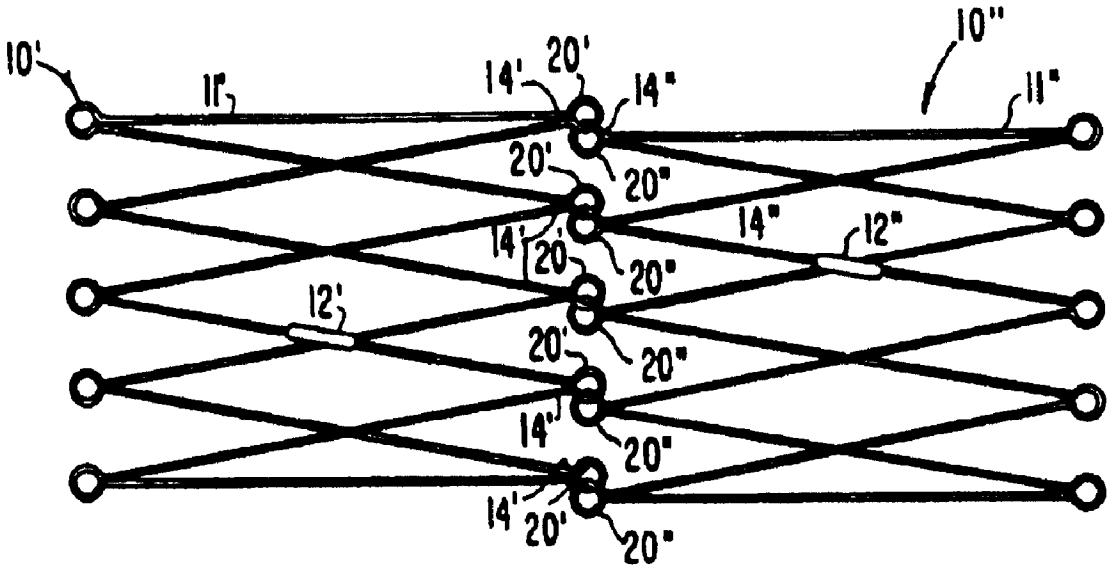
Primary Examiner—Jeanne M Clark

(57) **ABSTRACT**

A self-expanding stent formed of stainless steel wire arranged in a closed zig-zag configuration includes an endless series of straight sections joined at their ends by bends. The stent is compressible into a reduced diameter size for insertion into and removal from a body passageway. The bends of at least one end of the stent are formed into eyes for connection with the eyes at one end of a similarly constructed stent to permit single-step introduction of several lengths of stent into the passageway. A stent can include a monofilament thread passing through successive eyes at one end of the stent, the thread passing through each eye at least once and through some of the eyes a second time. The trailing ends of the thread extend from the stent and outside the body passageway. The stent can be retrieved from the body passageway by threading a tube of the free ends of the thread until the tube is adjacent the stent. The diameter at one end of the stent is reduced by pulling the free ends of the thread through the tube. A sheath concentrically disposed over the tube is introduced into the body passageway and over the remaining length of the stent to further compress the stent for removal from the passageway.



EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

NO AMENDMENTS HAVE BEEN MADE TO THE PATENT

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims **6** and **12** is confirmed.

Claims **1**–**5** and **7**–**11** were not reexamined.

* * * * *